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# *The Maryland Pharmacist*

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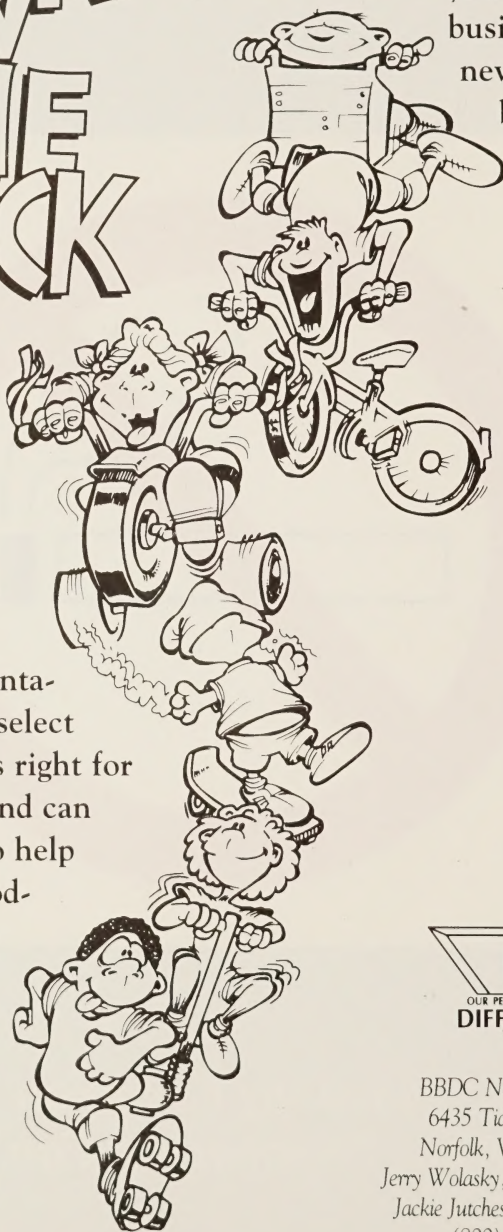


*Smoking Cessation  
What Pharmacists Can Do*

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# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association  
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Volume 68

Number 1

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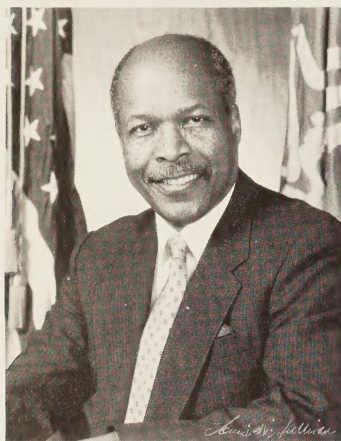
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## How Family Pharmacists Can Lead the Fight Against Smoking

### *A Special Message from Louis W. Sullivan, M.D.*

*Secretary of Health and Human Services, US Department of Health and Human Services, Washington, DC*



Across our nation, the American people are organizing to promote good health and to oppose products that cause disease, disability, and death. Pharmacists, in particular are well positioned to educate the public about health promotion and disease prevention. They ought to lead the movement to encourage smokers to stop and to discourage non-smokers from starting. **Because cigarette smoking is the leading preventable cause of premature death and disability in our nation.** Pharmacists not only can help the nation save the \$52 billion annually that smoking costs all of us -- smokers and nonsmokers alike. More importantly, family pharmacists can help us save some 390,000 lives annually.

Tobacco companies are hard at work today targeting blacks, latinos and young women with special brands and advertising designed to stimulate their cigarette consumption. They target male and female audiences with images and suggestions that smoking gives them the good feelings associated with the outdoor life of the West. They sponsor auto races to win the support of our youth who are attracted to motor sports. Cigar smoking is promoted to young men as a way of celebrating the success in their lives. The marketing of smokeless tobacco products is equally pernicious because they can lead to deadly cancers of the mouth.

Why do the tobacco giants target new consumers? **Because their product is killing their customers at the rate of more than 1,000 deaths every day -- thus, there is a constant search for new users.** Cigarettes and smokeless tobacco are the only legal consumer products that will kill the user when used exactly as intended.

Every American should be part of their community's campaign *for* better, healthier, longer lives and *against* the efforts of tobacco companies to send us to an early grave by pushing their products on our most vulnerable citizens.

**Pharmacists have a major role to play.** You must do everything you can to prevent and diminish this pestilence and plague. Here are some ideas

- First, pharmacists who smoke should stop, for their own good and for the good of their customers -- especially their younger customers for whom they can be role models. It is wholly inappropriate that a health professional would dispense a life-saving prescription with one hand and then use a life-threatening product with the other.
- Second, pharmacists must demand vigorous enforcement of the laws in our 44 states that ban the sale of tobacco products to minors. In those six states without such laws, pharmacists should work to have similar laws enacted.

# Policy of the Maryland Pharmacists Association

## *As Adopted by the MPhA House of Delegates*

- Third, pharmacists ought to use the "Pharmacists Helping Smokers Quit" materials developed by the National Cancer Institute with the American Pharmaceutical Association. Use these informational displays to warn smokers of the deadly dangers they face and the interactions smoking can have with some medications. Encourage your customers to make the personal choice against smoking and for life.
- Fourth, refer customers to stop smoking clinics and provide those clinics with space to promote their service.
- Fifth, prohibit smoking in your pharmacy, where people with allergies and life-threatening heart and pulmonary problems wait for prescriptions, information and advice.

We have to make a difference now. Remember it takes more than high technology to save a life -- it also requires a high sense of purpose. In the few minutes it took to read this article, **seven people died because they were smokers**. As health professionals, pharmacists are personally committed to saving lives -- and the loss of 1,000 lives a day is reason enough to help lead the fight against smoking.

---

*Secretary Sullivan's message originally appeared in The SmokeFree Pharmacy, a newsletter from Pharmacists for NonSmoking Families. For further information or to obtain a subscription to this newsletter, write John Pilgrim, Editor, Pharmacists for NonSmoking Families, 8 West Pacific Avenue, Henderson, NV 89015. Reprinted with permission.*

*Whereas* smoking has been identified as the greatest preventable cause of premature death and disability from cardiovascular disease and cancer; and,

*Whereas* second-hand smoke (ie. smoke breathed in by non-smokers) has been similarly identified as a major risk factor for cancer, stroke, and heart disease; and,

*Whereas* the State of Maryland has the highest cancer death rate in the country; and,

*Whereas* all State of Maryland offices, large retail stores, and most health facilities have adopted non-smoking policies to assure a smoke-free environment; and,

*Whereas* the pharmacy practice site is a health facility that is frequented by many persons for whom tobacco smoke is a definite hazard to their health and well-being.

*Therefore be it resolved* that the Maryland Pharmacists Association strongly recommend and encourage that all pharmacies be smoke-free and that implementation of this policy be accompanied with appropriate public education programs, including the conspicuous posting of signs.

Adopted: June 19, 1991

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## Correspondence Course

### Smokeless Tobacco Products: Trends, Toxicology, and Pharmacist Involvement

by Thomas A. Gossel, R.Ph., Ph.D.  
Professor of Pharmacology  
and Toxicology  
Ohio Northern University  
Ada, Ohio

and

J. Richard Wuest, R.Ph.,  
Pharm.D.  
Professor of Clinical Pharmacy  
University of Cincinnati  
Cincinnati, Ohio

#### Goals

The goals of this lesson are to discuss current trends in use of smokeless tobacco, relate product use to specific health risks, and suggest points to convey to consumers who are interested in undertaking a cessation program.

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#### Objectives

At the conclusion of this lesson, successful participants should be able to:

1. identify trends in the use of smokeless tobacco products;
2. choose the correct terminology that relates to smokeless tobacco use, and pathology associated with it;
3. select specific health risks associated with smokeless tobacco use and explain the pharmacologic/toxicologic basis for the risk, when known; and
4. demonstrate knowledge of suggested information to convey when counseling consumers on smokeless tobacco use.

Tobacco is addicting! It makes little difference whether it's smoked, macerated in the mouth, or sniffed into the nose. Tobacco, specifically nicotine, is as addicting as opioids, cocaine, or other illicit drugs of abuse.

Many users report that they partake of smokeless tobacco because they enjoy its taste. In fact, a recent study concluded that it was harder to quit smokeless tobacco use than stop smoking cigarettes.

This article will help pharmacists become more knowledgeable about smokeless tobacco products. It discusses contemporary trends in their use, and suggests reasons for them. It identifies specific pathology associated with its use, and lists the pharmacologic/toxicologic rationale for these changes, when known. It also

discusses activity underway to limit the use of these products. For users who express an interest in learning more about the products and their adverse health consequences, it provides specific information for pharmacists to convey to them.

#### Historical Perspectives

Tobacco was used by native Americans long before Columbus first visited the new world. Indian folklore dates its use back at least another 500 years, and information from archeological discovery suggests that tobacco may have been cultivated in North and South America as early as 5000 years B.C.

With its introduction to Europe and the rest of the world by early voyagers, tobacco use was a colorful part of history. This is certainly true of smokeless forms. Tobacco leaves were pounded into fine powders for sniffing deep into the nostrils, and minced into coarse cuts for chewing or holding in the mouth. A large percentage of the world's population over the years reportedly learned that tobacco conferred a variety of pleasurable and/or medical sensations, and they spent many hours each day chewing, sniffing, snorting, or smoking tobacco.

Its medical applications were of special interest. Smokeless tobacco products were recommended as first-line therapy to combat a variety of the ills of the day, including gastrointestinal afflictions, toothache and nasal congestion. An advertisement of years-gone-by proclaimed: "My nose is all stopped up I fear! It needs a dose of snuff to clear."

Use by Americans flourished throughout the 19th century and into the first decade of the 20th. But strong opposition was mounting regarding possible adverse health consequences of disposing of the major by-product of smokeless tobacco use — saliva — in public places.

By then science had linked spitting with tuberculosis, which was a major

cause of death at that time. Opponents publicly proclaimed dissatisfaction of users who required a place to expectorate their spittle. It became socially unacceptable and illegal to spit in many public places.

The movement against use continued, and ultimately opponents won their battle in 1913 when the first commercially manufactured American cigarette, Camels, appeared on the scene. This, along with invention of the cigarette rolling machine, offered smokeless tobacco users a relatively inexpensive alternative form of tobacco that didn't require the use of spitting or cuspidors. There was a massive switch to smoking, and cigarettes largely supplanted smokeless tobacco product use.

With the Surgeon General's proclamation a half-century later that smoking may be injurious to health, and mounting evidence that smoking is the primary preventable cause of death in America, many smokers were led to believe that unlit tobacco was safer than tobacco that was burned. Manufacturers of smokeless tobacco products recognized an emerging fertile market. They directed advertising efforts at conveying the image that a user was a strong, rugged, machismo all-American hero, tactics that are still used today.

In the early 1970s, millions of Americans, including a whole new generation of users — teenagers — began to use the products in record quantity. It is also tempting to speculate that the popularizing of styrofoam cups at that time also helped bolster smokeless tobacco use. They provided a portable, disposable cuspidor.

## Who Uses Smokeless Tobacco and Why?

In earlier years smokeless tobacco users were often pictured as uneducated "shoeless hillbillies" of low economic and social status from poor regions of the country. If this description were formerly true, it is now obsolete. Today, users represent all socioeconomic and educational classes. They live in all parts of the country, although use is greatest in the south, and lowest in the northeast.

Terminology that describes products and their use is defined in Table 1.

Prevalence of contemporary use can be estimated from sales, increasing

Table 1
Smokeless Tobacco Terminology
<b>Snuff:</b> Loose, ground-up, dry ("Scotch") or moist ("Snoose") tobacco. Processed as a flavored, sweetened, salted and/or scented product. Sold in loose form, either packed in cans or in "tea-bag" pouches.
<b>Chewing tobacco:</b> Loose-leaf tobacco, marketed in a large, folding pouch.
<b>Chaw:</b> A golf ball-size wad of leaf or plug tobacco. The amount of tobacco removed from pouch with thumb, index and middle fingers.
<b>Dip:</b> See "Snuff dipping"
<b>Plug tobacco:</b> Compressed leaf tobacco sweetened with molasses, licorice or sugar, and sold as flat bars or rolls.
<b>Twist tobacco:</b> Stemless tobacco leaves. Marketed as lightly twisted rolls.
<b>Snuff dipping:</b> Practiced by securing a pinch of loose, ground tobacco between the thumb and forefinger, and placing a <b>dip</b> (small portion of tobacco) between the cheek and gum and sucking the <b>quid</b> (moistened tobacco). Once in the mouth, the quid is generally confined to one area.

about 11 percent per year since 1970. In 1986, annual sales of smokeless tobacco products in the U.S. exceeded \$1 billion. Sales of moist snuff were more than 30 percent higher than five years earlier, while chewing tobacco sales declined by 3.5 percent, and dry snuff sales remained constant. Moist snuff is now the predominant form used in America.

In the early 1970s, the majority of users were elderly men. Today, reports are common that up to 30 to 40 percent of adolescent males use smokeless tobacco. One national survey indicated that 60 percent of males between 12 and 17 years of age had used smokeless tobacco during the previous year.

The percentage of use within age groups declines with increasing maturity; the number of users in their 40s and beyond has decreased. It is clear that the use of these products is a trend of younger Americans. Tragically, wide usage is reported in pre-adolescents. Up to one-half of elementary schoolboys surveyed uses smokeless tobacco, many of them at very young ages.

In America, the use of smokeless tobacco is primarily a habit of white males. Females seldom use it. The typical user dips or chews 2 to 8 times per day, for a total of 3 hours.

Results of a questionnaire answered by 5,894 college students and published in 1989 revealed other interesting statistics. Twenty-two percent of men and 2 percent of women were users. Asked why they used smokeless tobacco, 66 percent said they liked it. Another 23 percent admitted they

were addicted. The remainder said it made them look grown up, or they used it socially because of friends.

It's interesting that professional athletes, notably baseball players, inadvertently promote the products among young people. A 1987 survey of 25 teams in both major leagues revealed that 46 percent of players, 35 percent of managers and coaches, and 30 percent of trainers use these products. Product containers are often visible in uniform pockets as well as a chaw in their mouth. Young sports fans wish to emulate their heroes, and believing that product use is acceptable, try it themselves. Then, they're hooked!

The National Collegiate Athletic Association (NCAA) reports that 31 percent of professional athletes from many different sports actually started using smokeless tobacco during or after their freshman year in college.

## Physiologic and Pathologic Changes Associated with Smokeless Tobacco

Cigarette smoking poses a greater danger to health than unburned tobacco, but use of the latter is not without risk. The Surgeon General reported in 1979 that "...snuff and chewing tobacco have not been found to increase mortality (either overall or cause-specific) in the United States." By 1982, the annual report stated that long-term use of snuff appeared to be a factor in the development of cancers of the oral cavity.

Today, there are still many more questions than answers about physiologic and pathologic changes associat-

Table 2

**Physiologic and Pathologic  
Consequences of Smokeless  
Tobacco Use**

- Discolored teeth and restorative material
- Decreased ability to taste and smell
- Bad breath
- Tooth loss
- Excessive tooth surface wear
- Slower healing of cuts and sores in mouth
- Gingival recession
- Gingivitis
- Oral mucosal lesions (e.g., leukoplakia)
- Oral cancer
- Systemic effects
  - Cardiovascular
  - Metabolic
  - CNS
  - Endocrine
- Addiction to nicotine
- Fetal and neonatal toxicity

ed with use of smokeless tobacco. Some known facts are listed in Table 2.

**Gingival Recession.** Common among smokeless tobacco users, gingival recession, the wasting away of gum tissue, occurs in up to 60 percent of teenage users. Gingival recession is site-specific, with tissue migration such that tooth roots are exposed. This increases tooth sensitivity, and exposes root surfaces to the vulnerability of decay. Gum tissue does not regenerate. It can only be repaired surgically with great difficulty, if at all.

**Gingivitis.** Gingivitis is defined as clinically detectable acute or chronic, local or general, inflammation of the gums (gingiva). Data relating gingivitis to smokeless tobacco use are scarce and conflicting.

**Oral Mucosal Pathology.** There is a definite association between oral mucosal pathology and smokeless tobacco use. Leukoplakia is a leathery, wrinkled-appearing lesion with white striae and deep fissures. Lesions are sometimes elevated, and diffusely demarcated from surrounding mucosa. They are often asymptomatic. The literature recognizes the terms "snuff dipper's keratosis" and "snuff dipper's patch" as leukoplakia.

Leukoplakia lesions are precancer-

ous, with a malignant transformation rate of about 18 percent. Two studies of high-school students confirmed the incidence of leukoplakia plaques from use to be 43 to 62 percent. Lesions form most commonly in the oral cavity at the site of quid placement, and in heavy and long-term users.

**Oral Cancer.** The first positive link between smokeless tobacco and oral cancer appeared in 1915. Another 646 documented cases were cited in the medical and dental literature between 1915 and 1972. Recently, the Surgeon General reported that its use increases the risk of cancer of the gingiva and buccal mucosa by 50 times.

The data for adversity are stronger for snuff, than chewing tobacco. Nearly 90 percent of oral cancers are linked clinically to tobacco use. Typically, users who develop oral cancer have a long history of heavy use; but in some cases, oral cancer develops with short-term use. The most common site is the buccal mucosa.

There are an estimated 25,000 new cases of oral cancer discovered each year, with more than 9,000 deaths. The most common type is squamous cell carcinoma, an aggressive lesion with a mortality rate of 40 to 50 percent within five years of diagnosing. Fortunately, oral cancer has a low malignant transformation rate. Disfigurement and disability are common in survivors.

Nitrosamines are the principle known chemical carcinogens in smokeless tobacco products. Formed during the processing of tobacco and when tobacco interacts with nitrite in saliva, nitrosamines are among the most toxic of all chemicals. They are alkylating agents that induce neoplasia at the site of contact with tissue. FDA prohibits sale of food and beverage products if nitrosamine levels exceed 10 parts per billion (ppb). Concentrations of nitrosamines at 5,900 to 289,000 ppb are reported in various brands of smokeless tobacco. There is no government restriction on their sales.

In addition to the 19 nitrosamines identified, other carcinogens have also been isolated. Three toxic radioisotopes include Polonium-210, Radium-226, and Lead-210.

Whether cancer at sites other than the mouth can be linked to smokeless tobacco is currently inconclusive. There is a strong correlation between digestive and respiratory tumors, and its use. But evidence is less convincing

than for oral cancer.

**Tooth Decay.** Anecdotal evidence has associated the use of smokeless tobacco with both increased and decreased prevalence of dental caries. Products may contain a high concentration of carbohydrate which bathes the teeth with cariogenic sugars and promotes tooth decay. Severe, degenerative changes in salivary glands and ducts have been noted. If these structures are significantly affected, the resulting reduction in salivary flow would increase susceptibility to dental caries. Firm evidence of this relationship is still lacking.

Early-on in smokeless tobacco product use, salivary flow is enhanced. Increased saliva helps protect against tooth decay. Moreover, the products contain fluoride, which is carioprotective. It is therefore difficult to assess the role of smokeless tobacco in development of caries.

**Systemic Effects.** Regular users may not realize there are numerous systemic effects associated with smokeless tobacco use. Nicotine is the ultimate cause of disease. The alkaloid is rapidly absorbed across the oral mucosa to reach peak blood concentrations comparable to those from smoking, and is distributed throughout the body. Blood levels are also more sustained than following cigarette or cigar smoking. An average absorption of 4.5 mg nicotine from chewing tobacco and 3.6 mg from snuff is expected. An average of 1 mg nicotine is absorbed per cigarette.

Pharmacologic effects of nicotine are complex and extensive. In general, actions are consistent with activation of the sympathetic nervous system. Cardiovascular effects include an increased heart rate of 10 to 20 beats/minute, and blood pressure of 5 to 10 mm Hg. Prostacyclin synthesis is inhibited, and may enhance blood coagulation.

Metabolic actions result from elevated levels of circulating catecholamines which may contribute to increased total cholesterol and reduced HDL levels. On the central nervous system, arousal or relaxation, electroencephalographic changes and tremor are noted. Endocrine actions include increased growth hormone release.

Smokeless tobacco products can be a rich source of sodium (Table 3). Since some people use one or more containers of product each day, the amount ingested can be significant.

Table 3

## Sodium Content of Selected Smokeless Tobacco Products\*

	Container size (Gm)	Sodium/container (mg)
<b>Snuff</b>		
Copenhagen	34	1078
Happy Days Mint	34	1201
Kodiak	34	1126
Skool	34	1150
<b>Loose-leaf</b>		
Beech-Nut	85	829
Big Red	85	822
WB Cut	34	1044
<b>Plug</b>		
Bloodhound	45	795
Brown's Mule	45	533
Days-O-Work	70	1020

\*NEJM 312:919, 1985

As indicated earlier, tobacco is addicting. In studies of teenagers who attempt to quit smokeless tobacco usage, only a small number are able to do so. Although users report serious adverse consequences, they continue to use the products. Some even relate using smokeless tobacco during sleep. Withdrawal symptoms begin within hours of cessation. Former users continue to crave the products.

**Fetal and Neonatal Toxicity.** Tobacco contains toxic substances including nicotine, lead and cadmium, that can injure the fetus. These same toxins reach significant concentrations in breast milk and can be injurious to suckling infants.

## Fighting the Battle

There are numerous educational programs underway to curb the expanding use of smokeless tobacco. These are sponsored by various groups such as the American Cancer Society.

In February, 1986, President Reagan signed into law "The Comprehensive Smokeless Tobacco Health Education Act" (PL-99-252). This legislation banned television and radio advertising for smokeless tobacco products. It directed the Secretary of HHS to inform the public of the dangers of smokeless tobacco, and help state officials to do

likewise. PL-99-252 also required manufacturers to report annually to the Secretary, the ingredients in smokeless tobacco products, particularly chemical additives. It established 18 years as the minimum age for purchasing the products. And, it required manufacturers to display one of three rotating label warnings of health hazards on each product package and advertisement: "Warning: This product may cause mouth cancer;" "Warning: This product may cause gum disease and tooth loss;" and, "Warning: This product is not a safe alternative to cigarettes."

## How About Quitting Smokeless Tobacco Use?

A report published in 1986 concluded it was more difficult to stop using smokeless tobacco products than cigarettes. Recall, a majority of users in one national survey admitted they enjoyed the taste of the products.

A sizeable number of users apparently do want to quit, or have thought seriously about doing so. A survey indicated that 56 percent of users would try to quit within the next year. Forty-one percent of dental patients said they would be receptive to dentists' or hygienists' advice to quit. And 28 percent of high school males showed an interest in quitting.

## Pharmacists' Challenge

Health professionals, educators, parents, and school children need to be informed about adverse health effects associated with smokeless tobacco use. Pharmacists may wonder what they can do to help curtail continued growth of the smokeless tobacco market, especially since the predominant use of products is by young people. They can refuse to sell the products in their pharmacy. But that alone will not reverse current trends or stop usage since the majority of sales are transacted in non-pharmacy outlets. At minimum, electing to not supply the products sends a message to the community that shows pharmacists are interested in the good health of its citizens. The high level of public trust in pharmacists could be elevated even more.

There is a challenge for pharmacists; many users, especially younger ones, want to quit. Educational programs can be sponsored to make users aware of the health consequences. As part of community programs designed to inform about legitimate and/or illegitimate drugs, smokeless tobacco products could be included. Local branches of the cancer and heart associations, and the local dental association, can provide a vast resource of information on the topic. Taken into primary and secondary schools, such programs may make a significant impact on young people, and perhaps convince them it is not healthy to use the products.

For those users who cannot or do not wish to quit, two important points need to be conveyed. They should understand the importance of good oral hygiene. Also, they should vary the location of tobacco placement in their mouth to reduce the chance for oral pathology development. Much of the damage from smokeless tobacco products is due to placement of the quid at the same spot and leaving it there.

Will Nicorette help as an aid to smoking cessation programs? Nicorette is effective in assisting smokers to stop. While not officially indicated in smokeless tobacco cessation programs, there is support in the literature for its use.

Addiction to all tobacco products is due to nicotine. Nicorette provides nicotine while the user copes with the pharmacologic, sociologic and behavioral aspects of nicotine withdrawal. Therefore, the product may deserve a trial in cessation programs.

THE MARYLAND PHARMACIST

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## Smoking Cessation

*Trent Tschirgi, R.Ph.*

Drug Information Specialist

Office on Substance Abuse Studies

University of Maryland School of Pharmacy

Nicotine addiction in the form of tobacco product consumption shortens lives and causes needless death throughout the world. In the United States, "tobacco use is responsible for an estimated 390,000 deaths or about one-sixth of deaths from all causes.<sup>1</sup> A large proportion of cancer, heart and lung disease cases are caused by tobacco use. Once a person has started smoking, the likelihood of quitting successfully is small. There are only a few things that can enhance the chances of success in smoking cessation. Putting them into practice is a responsibility of the health care professional.

### Onset of Tobacco Use

Tobacco smoking is most often begun in early adolescence.<sup>2</sup> The first cigarette may be inhaled as a response to advertising, peer pressure, family environment, or combinations of the three.<sup>2,3</sup> Adolescents with one or more smoking parents are more likely to become smokers than those from tobacco-free homes.<sup>2</sup>

Peer pressure is a factor in the decision to smoke. It may be active or passive and is influenced by cultural factors. Young adolescents may see their peers use tobacco and feel out of place unless they also begin to smoke. This is an example of passive pressure to try tobacco products.<sup>4</sup> White adolescents in another study with a best friend who smokes were twice as likely to begin smoking as whites without smoking friends. However, this correlation did not hold true among black

adolescents, boys were found to be more affected by peer pressure than girls.<sup>5,6</sup>

Role models other than family and friends may influence the decision to try or use tobacco. Chewing tobacco is frequently used by major and minor league baseball players.<sup>7</sup> Since 1970, the prevalence of use has dramatically increased among high-school-aged baseball players in relation to the general population.<sup>7</sup> Seventh- and eleventh-grade students in one study<sup>8</sup> were more aware of sport sponsorship by tobacco companies than of advertising through normal channels--an effective way to associate sports role models with tobacco products.

---

***Tobacco use is responsible  
for an estimated 390,000  
deaths each year.***

---

Advertising plays a major role in making adolescents and pre-adolescents aware of tobacco products. Tobacco product advertising attempts to associate tobacco use with images of sports, style, health, leisure, and socialization. Adolescents in their period of development from 10 to 14 years old seek things that will enhance their social standing and self-image. It may not be a coincidence that "this time period is associated with a five-fold increase in cigarette smoking."<sup>9</sup>

Efforts to prevent smoking are, by contrast, ineffective.<sup>10</sup> One study of the effectiveness of public service campaigns on radio and television

found only a modest difference in adolescent attitudes towards smoking.<sup>11</sup> Television advertisements against smoking were no more effective than those on radio, and none of the publicity campaigns studied had any detectable effect on behavior. Tobacco use would be more easily handled as a health problem if it could be prevented. While there is evidence that over-all tobacco consumption has been declining since 1974,<sup>10</sup> there are currently about 50 million adult smokers in the US, 80% of whom would like to quit.<sup>12</sup>

### Mechanisms of Nicotine Addiction

Nicotine is the most addictive substance known to man.

Nicotine's high potential for addictiveness is related to some of its pharmacological properties. Most drugs with a high potential for abuse have a short half-life of elimination. The elimination half-life of nicotine is about two hours, shorter than that of most schedule I abused substances.<sup>13</sup> The body exhibits rapid neuroadaptation to the toxic effects of nicotine.<sup>2</sup> This results in a rapid onset of nicotine craving upon withdrawal from tobacco.

Withdrawal may last for days to weeks after smoking cessation depending on the individual's smoking frequency and the number of years she/he has been a smoker. Nicotine withdrawal begins within 24 hours of the final cigarette, and involves nicotine craving, drowsiness, irritability, and anxiety. While these

effects diminish rapidly over the first ten days of abstinence, former smokers complain that "problems such as increased appetite and inability to concentrate may persist for weeks to months."<sup>13</sup> Three-fourths of smokers who make an attempt to quit are smoking again within six months.<sup>14</sup>

Adolescents feel that they can try smoking a cigarette or two without risk of nicotine dependence. In fact, the opposite is true: Up to two thirds of adolescents who smoke even two cigarettes will become lifetime smokers.<sup>15</sup>

---

***Three-fourths of smokers  
who try to quit start  
are smoking again within  
six months.***

---

#### **Goal: To Stop Smoking**

A worthy goal for any health professional is to encourage people to stop smoking and to enable them to do so. If the elimination of smoking was simply dependent on the pharmacological characteristics of nicotine, drug treatment alone could handle it.

The pharmacist should be aware of the many non-pharmacological factors that can affect the success or failure of a person's effort to stop smoking, as well as knowledgeable about pharmacological agents that can help a person quit.

#### **Factors that Discourage Quitting**

However, there are social and psychological aspects to the smoking problem that interact to complicate the picture. What if a husband and wife both smoke, but only one wants to quit? What if one's friends and co-workers continue to smoke? In such cases, successful withdrawal from nicotine is not likely.<sup>16</sup> Working conditions may favor maintenance of a smoking habit. A registered nurse once told this author that she continued to smoke in order to have

a legitimate reason to take a break from work.

Nicotine decreases hunger. Consequently, smokers weigh 5 to 10 pounds less on average than their non-smoking counterparts of the same age and sex. When a smoker quits, she/he will most likely gain that 5 to 10 pounds over a period of a few months. This can have profound negative effects on the person's self-image and may provide one more reason to return to smoking.<sup>18</sup>

#### **Factors That Encourage Quitting**

Social and psychological factors may also reinforce the desire to stop smoking. Usually, a smoker has a compelling reason to want to quit. The strength of this reason to stop smoking and the degree to which it motivates the patient may be a deciding factor in the success of the effort. Seven of every ten attempts to quit smoking end in relapse.<sup>2</sup> However, smokers that keep attempting to quit are more likely to be successful in the long run.<sup>12</sup>

A patient may be under physician's orders to stop smoking for specific health reasons. The threat of a second heart attack or the slow death of a smoker's parent from emphysema are only two medical reasons for a smoker to decide to quit.

At smoke-free workplaces, there may be a stigma attached to the smoker. The necessity to go outside the building to smoke even during cold or inclement weather may be a motivation to quit. Whatever the reason, the active support of peers and family members help a smoker to concentrate on dealing with the pharmacological effects of nicotine.

#### **Non-Drug Therapies**

Non-drug methods include "cold turkey," and hypnosis. These may be used alone or in conjunction with drug treatment. Abstinence without these drugs must be conducted with strong social support in order to be effective.<sup>16</sup> Results from placebo groups of controlled studies indicate

that attempts to quit smoking without drug treatment or counseling have a failure rate of about 80%.<sup>20</sup>

Hypnotherapy is another non-drug option to stop smoking. The relapse rate associated with it is about 70%, and thus not significantly different from other active treatment methods.

#### **Drug Therapies**

Currently, OTC products marketed in the US to alleviate nicotine craving have not been demonstrated to be effective and are a best only slightly better than placebo.<sup>20</sup> Use or non-use of OTC products is left up to the judgement of the health professional dealing with the individual case. Following are outlines of OTC products available, along with some other agents that have potential as OTC smoking cessation aids.

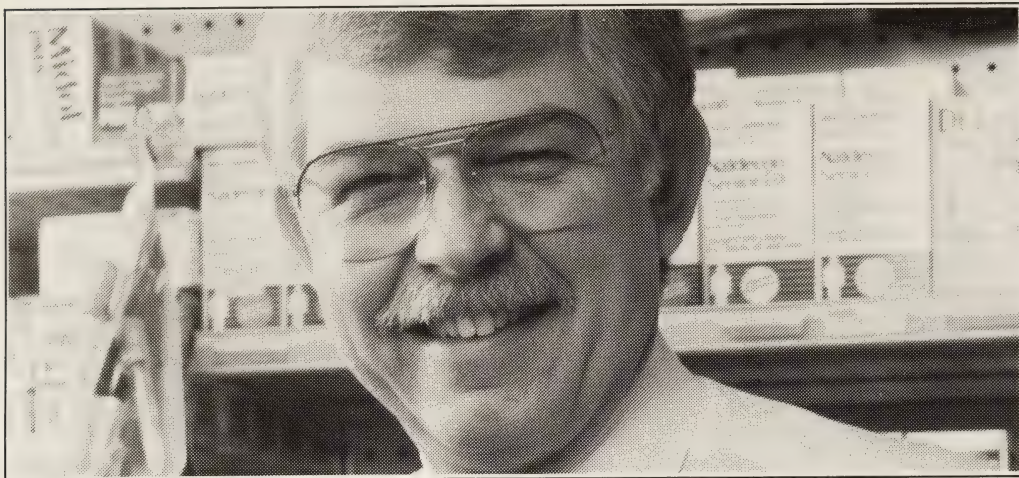


#### **OTC Products**

**Lobeline:** An alkaloid from *lobelia inflata*<sup>21</sup>, also known as "asthma weed" and "wild tobacco".<sup>22</sup> Lobeline is an alkaloid with properties similar to those of tobacco at the neuromuscular junctions. Lobeline sulfate tablets, 2 mg (Bantrol) have potentially severe side effects. An 8 mg acute dose may produce "epigastric pain, severe heartburn, belching, nausea, vomiting, and faintness."<sup>21</sup> It is in FDA OTC Category III-- safety, but not efficacy, has been established.

**Silver Acetate** Taken in form of chewing gum, Silver acetate produces unpleasant taste in the mouth when

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tobacco products are used.<sup>23</sup> One study<sup>3</sup> indicated a marginally significant benefit over placebo to prevent smoking relapse in the absence of a program of assistance to stop smoking. Another study<sup>24</sup> indicated a non-significant difference between silver acetate gum and placebo. It is currently in FDA OTC category III--safety, but not efficacy, has been established.

**Glucose tablets:** Tobacco craving is thought by some to be associated with changes in glucoregulation.<sup>25</sup> This may explain descriptions of tobacco cravings as "like a gnawing hunger" In a recent study,<sup>25</sup> smokers in a clinic were given either glucose or sorbitol tablets and instructed to chew them when experiencing craving. The glucose group reported "significant reductions in ratings of urges to smoke and craving" over the sorbitol group.<sup>25</sup> The results are of unknown significance, since all subject were also using nicotine gum and the sample size was small. However, glucose tablets are low in cost, and may be at least as effective as other OTC quit-smoking aids.

**Citric Acid Aerosol:** "Taste" is often cited by smoker as a reason to smoke cigarettes high in tar and nicotine. The "taste" sensation for a

smoker has more to do with the impact of smoke in the trachea than with the actual "taste" or smell of tobacco smoke.<sup>26</sup> A citric acid aerosol inhaled by volunteer smokers was rated as equivalent in "taste" satisfaction to that of a low tar and nicotine cigarette.<sup>26</sup> After inhalation, the desire to smoke a cigarette was significantly reduced.<sup>26</sup> No commercial citric acid aerosol product is commercially available at this writing. However, it is probably within the compounding capabilities of most retail and hospital pharmacists to make the 15% aqueous solution of citric acid and dispense it in a pump-spray bottle. Such an aerosol, if demonstrated to be effective, could be a low-cost, low-toxicity alternative to other drug therapies on the market.

Commercially available products such as "EZ Quit" contain essential oils and ethanol in a cigarette-like inhaler. They may work on the same principle as the citric acid aerosol.

#### Prescription Products

**Nicotine Gum:** The only officially-approved prescription adjunct at stopping smoking in the US is nicotine polacrilex gum (Nicorette).

It is intended for use only in conjunction with a behavioral smoking cessation program, and has not been demonstrated effective if used for more than three months.<sup>27</sup> When used as directed, nicotine gum in conjunction with clinical support has a 30% success rate after one year versus a 20% success rate for placebo with clinical support).<sup>28</sup>

In actual practice, 99.5% of nicotine gum users receive it after only a brief visit with a physician.<sup>29</sup> Patient histories of nicotine gum use extending longer than a year are not uncommon. As stated previously, there may be a cultural reluctance to participate in smoking cessation programs that partially accounts for this extensive departure from protocol.

---

*As few as two  
cigarettes can lead to  
a lifetime smoking habit*

---

The patient should stop smoking completely before beginning to chew the gum. Gum should be carried with the patient and chewed when here is craving for nicotine. The chewing action releases nicotine from its polacrilex carrier. When craving stops, the patient should park the gum in the buccal area, chewing again when craving recurs. After 30 minutes of chewing, 90% of the nicotine will have been released from the gum.<sup>27</sup> Patients should be advised to chew slowly, to chew only chew one piece of gum at a time, not to swallow the gum and to keep gum with them at all times during therapy. An initial recommended regimen is 1/2 to 2 pieces of gum chewed per hour while awake.<sup>30</sup> No more than 30 pieces of gum should be chewed in a 24-hour time period. The total number of pieces of gum chewed per day should be decreased over a period of two to three months.<sup>27</sup> The rate of gum consumption can easily be monitored with computerized patient profiles currently available.

*Nicotine Transdermal Patch:*

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Dermally-absorbed nicotine is a new dosage form currently undergoing investigation as an adjunct to smoking cessation. Patches releasing 16 mg of nicotine per day approximate nicotine blood levels obtained by chewing nicotine gum.<sup>20</sup> In a study that administered the transdermal patches with minimal counselling, there was a 36% success rate with the patch versus 23% with placebo.<sup>20</sup> The 67% failure rate is about on par with that of other treatment modalities.

**Clonidine:** Oral clonidine has been used as an adjunct to alleviate craving for nicotine. In a study of fifteen heavy smokers, clonidine 0.2 mg was giving orally and the results compared to placebo and alprazolam on three separate 90-minute trials<sup>31</sup>. There was a strong correlation between reduction of craving and administration of clonidine. This was attributed to the central alpha-2-noradrenergic agonist activity of clonidine. Smoking cessation is not an officially approved use for clonidine, although efficacy in smoking cessation has been established.<sup>32,30</sup>

**Clonidine Patch:** Since craving may occur for weeks after smoking cessation, the use of a clonidine transdermal patch may enhance patient compliance. Clonidine patches take up to 3 days to become effective. Oral clonidine should be continued and tapered after beginning the transdermal dosage route. Although clonidine patches come in sizes designated "1, 2 and 3", the dose of clonidine absorbed from each does not necessarily correspond to the 0.1, 0.2 and 0.3 mg oral tablet strengths.<sup>27</sup>

### Professional Opportunities

Now that you have considered some of the available information on quitting smoking, all that remains is to apply it to your pharmacy practice. In a day of increasing competition, it is often helpful to develop a specialty practice "niche" that will enable you to offer something to the patients and physicians in your area which is not offered by anyone else. For some, it

may be possible to develop a specialty in smoking cessation.

### Counseling and Patient Monitoring

Retail pharmacists have several advantages in smoking cessation: While almost all smokers are resistant to the concept of support group treatment and monitored progress when attempting to quit, they will come and see you regular to get their prescriptions refilled. A note in the profile and a quick check of refill frequency is all that is necessary to see whether your patient is in fact decreasing the number of pieces of nicotine gum chewed, or is taking it beyond to recommended three-month efficacy. counseling and social reinforcement are associated with success in kicking the tobacco habit. Pharmacists are in an excellent position to provide both if they are willing to take a few minutes to have a personal and professional interest in their patients.

---

### *Helping your patients stop smoking can increase your professional reputation*

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### Business and Entrepreneurial Opportunities

Besides commercially-available OTC, the pharmacist will be able to recommend toe oral glucose tablets used for hypoglycemia in diabetics as adjuncts in treatment. Compounding aficionados will be able to dispense their own citric acid pump inhalers, an entrepreneur could probably work out an agreement with a local medical practice group to try out the citric acid pump inhaler on a group of smokers. Offer an HMO a way to withdraw patients from smoking that is less expensive than nicotine gum and effective, and you will have a very nice business niche. They might pay for a study to demonstrate effectiveness.

Many pharmacies use screening

tests and educational events as a way of promoting their health services. Smoking cessation can be a topic for such a promotion. The National Cancer Institute publishes a comprehensive guide entitled, "Self-guided strategies for smoking cessation: A program planners guide (National Institutes of Health Publication 91-3104)." It gives strategies for carrying out various types of smoking cessation programs, along with the addresses of over 60 organizations that will send you literature in bulk at no charge, or for a nominal fee.

### Pharmacist Consulting

Clonidine treatment may be appropriate for certain patients as an alternative to nicotine gum. The oral form of clonidine would certainly be less expensive, and the transdermal form of clonidine, while about the same in price, box for box, as nicotine, requires less patient effort to comply with therapy. By offering alternate therapies where your professional judgement shows that it is appropriate, you can demonstrate to the patient and the physician that you are interested in successful treatment and in saving the patient money. This can only enhance your professional reputation.

### Summary

The statistics on smoking cessation can be depressing. Current prevention efforts are ineffective, while tobacco advertising is effective in getting 10 to 14-year olds to smoke. As few as two cigarettes can lead to a lifetime smoking habit. Only 3 out of 10 smokers who try to quit are tobacco-free after a year. However, pharmacists are in a unique position to provide the types of services that will reinforce their patients' ability to stop smoking. There is opportunity in smoking cessation to promote the health of your patients and build on your professional reputation. Your patients and physicians will thank you for it. ■

# Smoking Cessation

Trent Tschirgi, R.Ph.

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## OBRA-90: One Year Later

### *A Special Report From the National Pharmacy Forum on Medicaid Drug Amendments*

The Omnibus Reconciliation Act of 1990 (OBRA-90), Public Law 101-508, enacted November 5, 1990, contains a number of provisions affecting Medicaid pharmacy programs and pharmacy providers. Discussions among several Medical pharmacy consultants revealed that a number of issues surround the implementation of OBRA-90 provisions for Medicaid pharmacy. As a result of these discussions a program, the National Pharmacy Forum on Medicaid Drug Amendments, was established to explore the issues in more depth.

The Forum program, funded by an educational grant from Lederle Laboratories consists of: a panel discussion and subsequent report, a survey of pharmacists, and a report containing the survey results. In addition, the Forum intends to develop pharmacist continuing education programs in areas where survey results indicate a need for additional education. The following is a summary of the tasks undertaken by the Forum as of October 25, 1991.

A panel was established with the cooperation of the following national pharmacy associations: ACA, APhA, ASCP, NACDS and NARD. This panel, consisting of Pharmacy practitioners identified by the national pharmacy associations or a representative from the association, Medicaid pharmacy consultants and a third-party fiscal intermediary, was convened on May 23, 1991 to address implementation issues.

The panel first identified issues facing the Medicaid pharmacy programs. The panel then determined that many of the provisions affecting Medicaid programs are also affecting pharmacy providers. Since pharmacists are substantially involved in a number of OBRA-90 provisions (e.g., dispensing only rebated products to Medicaid recipients, performing prospective drug use review), the panel was interested in defining those issues affecting pharmacy providers. Issues identified by the panel as most likely to impede effective implementation of the provisions include: inadequate time for implementation of regulations, insufficient information, and unspecified

guidelines for prospective drug use review. Recommendations to facilitate the implementation process were then provided by the panel and are presented in the Panel Report.

Following the panel meeting, a survey of approximately 80,000 pharmacists was conducted in order to assess pharmacists' awareness of OBRA-90 as well as their ability to comply with certain provisions of the law. Completed surveys were returned by nearly 13,000 pharmacists. While survey results indicate that pharmacists are well informed of the OBRA-90 provisions affecting them, it is apparent that some pharmacists are experiencing difficulty in complying with certain aspects of the regulations required by the law. For example, the survey results revealed that the majority of pharmacists indicated an inability to screen for many of the drug therapy items outlined in the OBRA-90 drug use review position.

The following table presents selected data from the returned surveys. The national or overall results of the survey appear in column one while the second column contains information from Maryland pharmacists. ■

#### *Selected Survey Results*

##### *How would you rate your ability to:*

*National    Maryland*

##### Dispense Only Rebated Products?

Easy	19.0%	14.0%
Somewhat Easy	25.3	25.2
Mid-Range	26.7	26.4
Somewhat Difficult	15.7	20.4
Difficult	13.3	14.0

##### Use Product's Specific NDC #? *especially for generics*

Easy	42.6%	41.3%
Somewhat Easy	19.2	23.1
Mid-Range	15.2	14.7
Somewhat Difficult	10.8	8.7
Difficult	12.1	12.2

***Maryland had a 28.1%  
response rate to the  
national survey***

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## The Control of Sales and Use of Tobacco Products: The Pharmacists' Role

Donald O. Fedder, B.S.P., Dr.P.H.

Associate Professor and Director, Community Pharmacy Programs  
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The smoking-attributable mortality in Maryland (1985 data) was 5,266 including 3,478 men, 1,727 women and 61 pediatric. Every Surgeon General since Elliot Richardson has labeled cigarette smoke as a major health hazard. HHS Secretary Louis W. Sullivan most recently called upon pharmacists to join the fight to eliminate smoking in the U.S..

As many readers of this journal are aware, I owned a pharmacy for more than 23 years -- one that sold all types of tobacco products. In addition, I was a regular smoker of both cigarettes and pipes. I recognize both the difficulties in quitting as well as the fact that sales of tobacco products are both profitable in and of themselves and are good traffic builders.

However, especially in the past decade, I have seen the effects of tobacco use, not only on patients, but on their families and friends. I have become convinced that pharmacists must reassess our role in the distribution of these products.

I was asked to write this article to suggest ways to help pharmacists assist their patients change their smoking behavior. Changing behavior is difficult at best, but is almost impossible unless those who make the recommendations begin with themselves. So let me first discuss some initial changes for you, the pharmacist.

There is no question in my mind that no one should be allowed to smoke in the area in which prescriptions are being filled. Neither smoke nor ash has a place where medication is being prepared. Similarly, since many patients are sensitive to the effects of tobacco smoke, the entire store should be a non-smoking area. Consider the effect on an asthmatic who must enter an environment polluted with smoke. Effecting these changes immediately in every pharmacy in Maryland will go a long way in helping not only our patients, but our image as well. And, this should not be difficult to accomplish, since State law presently requires that retail stores with more than seven employees be smoke-free.

Now, I can hear myself back in my pharmacy questioning whether I could advise my patients/clients not to smoke when I am selling cigarettes. I believe that

today I would have no problem since I am so aware of the tragic consequences of people smoking -- and of the consequences on the non-smoker who must breathe in smoke from someone else's cigarette.

Having placed this item on the agenda, how would one go about implementing these new policies? Well as in any behavioral strategy, all changes do not necessarily have to be implemented in one step. The first step in restricting smoking should be in the immediate environment of the prescription department. Neither store personnel nor patients/clients should be allowed to smoke. Once implemented, the next step to eliminate smoking in the entire store is relatively simple.

---

*Cigarette smoking is the chief preventable cause of death in our society. It is directly responsible for some 390,000 deaths each year in the United States, or more than one in every six deaths in our country. The number of Americans who die each year from diseases caused by smoking exceeds the number of Americans who died in all of World War II, and this toll is repeated year after year.<sup>1</sup> (emphasis added)*

---

Next, you might wish to re-evaluate the profitability of tobacco sales vis-a-vis your pharmacy mission as a health care facility. In my own case, I found that the professional portion of my business contributed 80 percent of the net profit and yet I had allocated only 20 percent of the store area to it. This led to my remodeling the pharmacy, adding professional products and downgrading what I once thought were essential items. The fear was that the elimination of these would cause my customers to leave in droves to my competition. In 1973, I discontinued all loose packages of cigarettes and sold only cartons. Cigarette sales fell, but my DME and ostomy sales more than made up for them. I never quite got to the point of discontinuing all tobacco sales before I sold the pharmacy

*Continued on page 22....*

in early 1974, but it wasn't too long before only the professional pharmacy remained -- and it continues to be quite successful to this day. Today there are no tobacco products sold at 201 Wise Avenue and yet the pharmacy continues to thrive.

#### Now, how about our patients!

More and more of our patients are interested in quitting. For many, the decision to stop awaits only a little nudge from a health professional. In fact, research has shown that if a physician will unequivocally say "As your doctor, I want you to stop smoking", three to five percent of patients will stop immediately. The pessimist will point out that 95 to 97 percent just keep on puffing -- and that's true. However, for the three to five percent of patients who do comply, their chances to live longer and better have been enhanced immeasurably.

Some patients will welcome your advice as well. It will help if you are a non-smoker who "lives" in a non-smoking environment. Others have considered quitting but are awaiting the right time to start. Those with some intention to quit should be your primary target. Persons who have thought about quitting need to be encouraged to develop a plan.

The following are suggestions for these people. Many of these are derived from material available from the American Heart Association-Maryland Affiliate. You may wish to reproduce these or get already prepared materials from AHA.

- Make a list of the reasons you want to quit. Concentrate on these, fixing them in your mind. Do they make sense? These reasons should be personal, not "only" that your doctor, your spouse or kids are hounding you.
- Based upon these reasons, make the decision that you want to quit.
- Set a "quit date." Put it on your calendar. It is a good idea to tell others of your decision to get their support.
- Hold it! You may not be quite there yet. Many people need to condition themselves for the change. You might start a modest exercise regimen, increase fluid consumption (but not alcoholic beverages), get plenty of rest and avoid fatigue. Tuck a piece of paper into your pack and note each time you smoke. This visual diary will help in setting strategies when the time comes to stop. In addition, you might collect the cigarette butts in a glass jar to remind you of the mess that smoking creates. Practice eliminating some cigarettes. Do not concern yourself with never smoking. Rather consider cutting down and then stopping for one day at a time. Experience with others found that this works best. However, you still must convince yourself that you won't smoke and then keep your word to yourself. Now you are almost ready to quit.
- Make an appointment with your dentist to have your teeth cleaned on the very day that you have set to quit.

#### Quit Day

- Throw away all cigarettes and matches. Eliminate all reminders, such as ashtrays and lighters.
  - Have your teeth cleaned.
  - Make a list of things you would like to buy yourself or someone else, estimating the value in terms of the money you will be saving by not smoking. For example, a two pack a day smoker will save more than \$100 a month or \$1,200 a year.
  - Keep busy. Make sure that you get to your exercise session or take a long walk. Celebrate your decision in some way. Avoid places where you found that you really want to smoke. This would include stopping at the bar on the way home from work or lighting up after a meal. Substitute another activity.
  - The first few days, spend as much time as possible in places where smoking is prohibited -- the movies, at work, the library, or at museums.
  - Force fluids, such as water and fruit juices, but avoid alcohol, coffee or any others that you normally associate with smoking. Some people reach for a substitute to satisfy the need to put something in either their hand or mouth. I found hard, preferably sugarless, candy helped me.
  - Get your clothes cleaned and shampoo your car seats. Try to eliminate the odor of smoke wherever possible. You will be surprised how quickly the smell of stale tobacco smoke will bother you. I found I had to even shampoo the carpet and drapes in my office.
  - Reward yourself regularly. There are many more things to do as you enter the non-smoking world.
  - Remember changes do not occur easily. For some they will not occur at all. Do not get discouraged with "failure." Many people go through several attempts to quit, some lasting months, before they finally quit for good. Recidivism or "back-sliding" is not a sin -- in fact, it's pretty normal. So just get started again, and sooner or later you will succeed if you really want to.
- Thousands of people have stopped smoking. Pharmacists have played an important role in the movement to make America "Smoke Free by the Year 2000." In fact, the American Cancer Society's "Great American Smoke-Out" campaign was initiated by California pharmacist Fred Mayer.
- For more information, and for materials to provide your patients, contact the American Heart Association-Maryland Affiliate, the American Cancer Society, the National Heart, Lung and Blood Institute (NHLBI) or the National Cancer Institute (NCI) for quit smoking materials. ■

<sup>1</sup>Louis W. Sullivan, Foreword in *Smoking and Health: A National Status Report*, 2nd Edition, DHHS Pub. No. (CDC) 87-8396 (Revised 02/90).

# Important figures in diabetes care



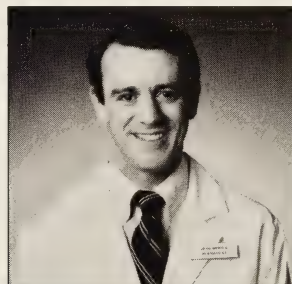
Diabetes is the **No. 7** cause  
of death in the US<sup>1</sup>

---



Diabetes is the **No. 1** cause of new  
blindness in persons aged 20-74<sup>1</sup>

---



Pharmacists see patients with diabetes  
**5** times more often than do physicians.  
These customers spend 3 to 8 times more  
annually in the pharmacy than persons  
without diabetes.<sup>2</sup>

---



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Your Lilly sales representative will visit you soon with  
information on a number of services and materials we  
can offer you and your customers with diabetes.

1. *Diabetes Surveillance, 1980-1987*. Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes*. Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

## Investing for Today *Investors Face Dilemma As CD Yields Sag*

Daniel K. Hays

If you're like many investors with CD's about to mature, you may be unsure about what to do with your money.

In the past, this decision was fairly straightforward. CDs offered attractive fixed rates of return and FDIC insurance. As a result, CDs were typically rolled over into new ones of the same maturity.

Today, however, that is not the case. Short-term rates on CDs have dropped considerably and are currently down to around 5 1/2%, significantly reducing the annual income earned.

The accompanying chart dramatically shows that current CD yields are much lower than they were as recently as seven years ago. For example, if you had \$100,000 invested in a one-year CD in September 1984, you would have earned on 11.60% yield or \$11,600 in annual income. That same CD purchased in September 1991 would generate only a 5.76% yield or \$5,760, nearly a 50% drop in annual income. And after inflation is taken into account, (current rate about 4%) the real rate of return or actual purchasing power of your money is even further reduced.

### Downward trend continuing

Previously some analysts believed that short-term interest rates has reached their cyclical lows. Now, however, owing to the sluggish nature of the economic recovery and the fact that the Fed may pursue an easier monetary policy in order to bolster the flagging growth in the money

supply, rates are expected to soften even more. In fact, some estimates call for short-term rates to decline by as much as 35 basis points (1 basis point is equivalent to .01%) by year-end.

Furthermore, some analysts believe long-term rates may also decline from a previous trading level of 8-8 1/2% to as low as 7% over the next 12 months.

### Factors to consider

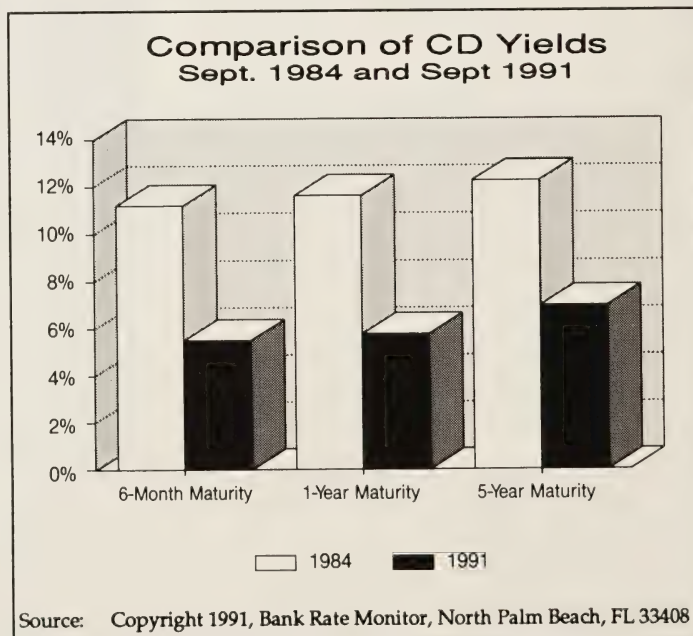
While rolling over your current CD may seem easier even though today's yields are so low, now may be a good time to evaluate other alternatives that offer the opportunity for higher yields and relative safety. Before you take any action, however, remember the relationship between risk and

return.

It is important to realize that prices of some fixed-income alternatives may vary with interest rate fluctuations and downgrades by credit rating agencies such as Standard & Poor's. These changes may affect the principal value of your investment.

Equally important is matching your time frame for investing with your financial goals. Generally, short-to-medium term maturities are less subject to interest rate fluctuation and earn competitive returns.

However, if interest rates are expected to decline, the potential for enhancing return is greater if maturities are extended. If you're planning for long-term goals like retirement or an education for your children, even a slightly higher return





# ARE YOUR RETIREMENT PLANS EXTINCT?

You have wonderful plans for retirement. Traveling, sailing, golfing. But they all take money. Money that you don't have -- yet. You thought that you could depend on Social Security and your pharmacy pension to see you through. But times have changed and that type of retirement planning is extinct. You don't know where to turn. Who to ask. What to do.

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Daniel K. Hays, Investment Consultant

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is worth pursuing to build assets for the future.

Here are a few investment alternatives to consider when rolling over your CD. They offer varying degrees of risk, flexibility and the potential for higher total returns.

There are intermediate-term Treasury Notes or longer term U.S. Government bonds; also GNMA's, CMO's, Zero coupon bonds or convertible securities. If you're a tax conscious investor, investigate the advantages of municipal bonds and annuities.

If you prefer not to invest in individual securities, open-end or closed-end mutual funds or unit investment trusts that specialize in government bonds, GNMA's, corporate or municipal bonds may be a more convenient way to manage your investment over the long term. While these pooled investment vehicles identify current taxable or tax-exempt income as their primary objective, they can also provide attractive total returns.

If you are unsure about which investments are suitable for your objectives and risk preference, ask a financial consultant for help. ■

Daniel K. Hays is a fellow MPhA member and investment consultant in Lutherville, Maryland. If you have any questions, he can be reached at 321-6900.



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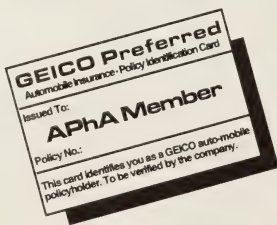
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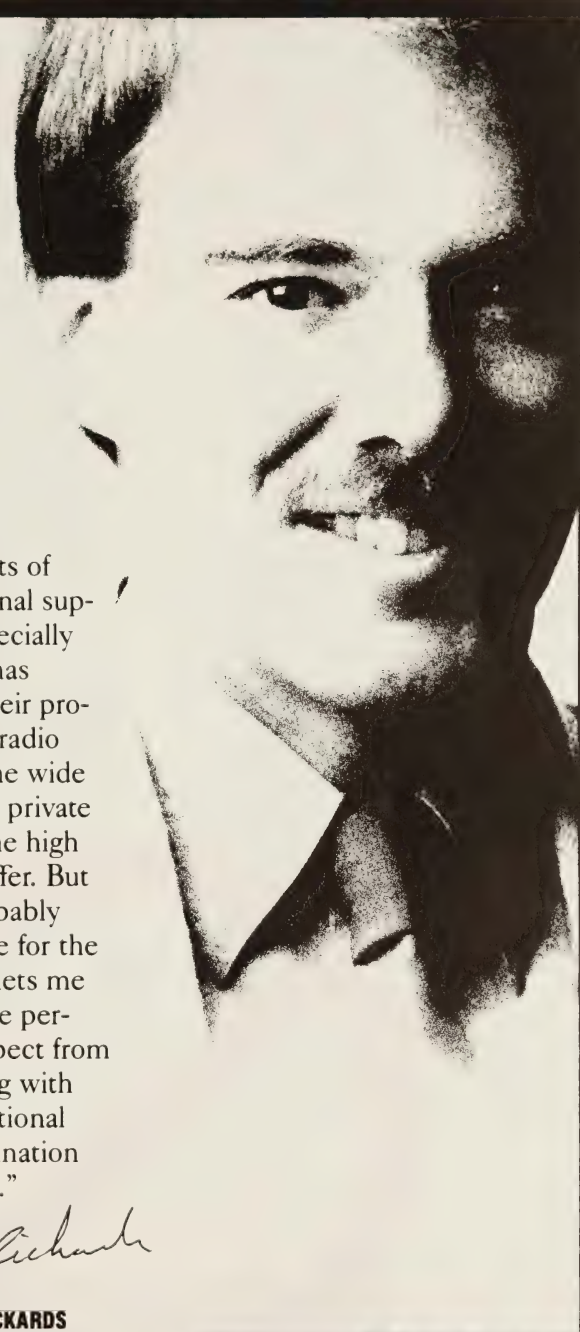
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OF OUR PATIENTS**

**PLEASE DO NOT  
SMOKE IN OUR  
PHARMACY**





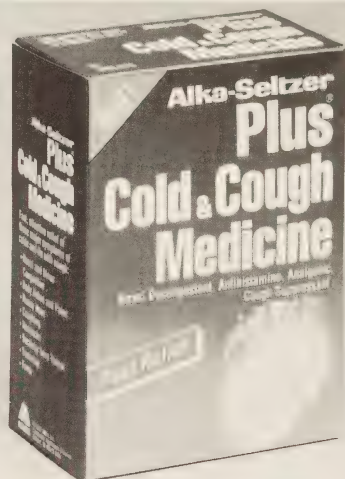
Barnett Laboratories has recently introduced XS Hangover Relief Formula, the nation's first multi-symptom OTC medicine specifically formulated to address all the unpleasant side effects from the over-indulgence in alcohol. The product includes a micro-pulverized aspirin-free pain reliever, an antacid and a stimulant. The product is available in 4 ounce bottles.



Tobramycin sulfate injection has been added to Lederle's growing line of injectable products. The antibiotic, indicated for treatment of a variety of bacterial infections, is available in both multi-dose vials and prefilled syringes.



Wheaton Industries has assumed 100% ownership of the Frueденberg/Wheaton Company, manufacturers of precision-molded rubber closures and aluminum seals for the health care markets. Now called Wheaton Pharmatech, the manufacturer's plant and facilities are located in Salisbury.



Miles, Inc. has introduced new Alka Seltzer Plus Cold & Cough Medicine, the only four-ingredient cold and cough product with an effervescent delivery system. Active ingredients include phenylpropanolamine, chlorpheniramine, buffered aspirin, and desmethorphan. The product is available in 20 and 36 tablet packages.

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# Continuing Education

## Continuing Education Quiz

*The Maryland Pharmacist*

JANUARY 1992

Complete and mail entire page with \$5.00 check, \$10.00 to non-MPhA members, made payable to Maryland Pharmacists Association, to: Maryland Pharmacist CE, 650 West Lombard Street, Baltimore, MD 21201. The completed quiz for this issue must be received by May 30, 1992. A continuing education certificate for one contact credit will be mailed to you within 30 days. Please type or print clearly.

Name \_\_\_\_\_

Social Security Number \_\_\_\_\_

Address \_\_\_\_\_

City/State/Zip \_\_\_\_\_

Is this program used to meet your mandatory CE?    ☐ Yes    ☐ No

Did this article achieve its stated objectives?    ☐ Yes    ☐ No

How long did it take you to complete the program? \_\_\_\_\_ minutes

### Smokeless Tobacco

1. Historically, strong opposition that mounted against the use of chewing tobacco in the early 1900s resulted when spitting was linked to the spread of:
  - a. influenza.
  - b. polio.
  - c. scarlet fever.
  - d. tuberculosis.
2. One of the toxicities caused by smokeless tobacco is a leathery, wrinkled-appearing lesion of the oral mucosa. The term that best defines this condition is:
  - a. hyperplasia.
  - b. leukoplakia.
  - c. nicotine necrosis.
  - d. cellulitis.
3. The most common site for smokeless tobacco-induced oral cancer is the:
  - a. buccal mucosa.
  - b. juncture of the gums and teeth.
  - c. side of the tongue.
  - d. uvula.
4. The predominant form of smokeless tobacco used in the U.S. is:
  - a. chewing tobacco.
  - b. dry snuff.
  - c. moist snuff.
  - d. plug tobacco.
5. According to the chart in the article, the sodium content per container of snuff is reported to be in the range of:
  - a. 0-499 mg.
  - b. 500-999 mg.
  - c. 1000-1499 mg.
  - d. 1500-1999 mg.
6. Which of the following poses the greater danger to health?
  - a. Cigarette smoking
  - b. Smokeless tobacco
7. Gingivitis refers to inflammation of the:
  - a. gums.
  - b. lips.
  - c. teeth.
  - d. tongue.
8. In the survey reported in this article, the leading reason given by respondents on why they used smokeless tobacco was:
  - a. it made them look grown up.
  - b. they were addicted to it.
  - c. social pressures.
  - d. they liked the taste.
9. After snuff has been placed between the cheek and gum, the moistened tobacco that results is called the:
  - a. chaw.
  - b. plug.
  - c. cud.
  - d. quid.
10. Nicotine absorbed from smokeless tobacco products causes all of the following actions EXCEPT:
  - a. increased heart rate.
  - b. increased blood pressure.
  - c. increased prostacyclin synthesis.
  - d. increased circulating catecholamines.

# Classified

"Rx" LICENSE PLATES are still available through MPhA. When you receive your license renewal form, contact Mary Ann at (410) 727-0746 for details. The plates say "Pharmacist Association" in addition to "RX" and the number. This offer is open only to members and their immediate family.

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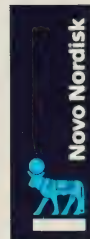
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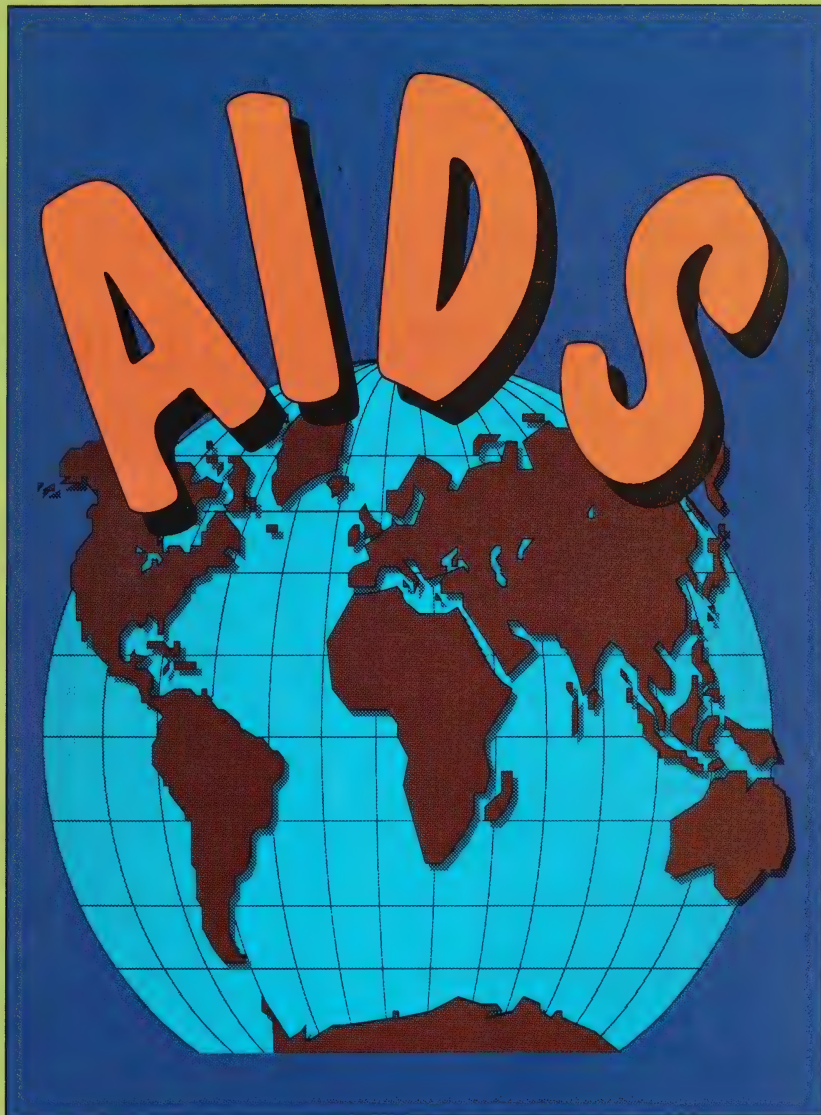
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# The Maryland Pharmacist

VOL. 68

February, 1992

No. 2



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# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association  
650 West Lombard Street, Baltimore, Maryland 21201-1572

February 1992

Volume 68

Number 2

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Richard D. Baylis, P.D., F.A.S.C.P.

Director, Maryland Drug Utilization Review



Since 1981, more than 200,000 Americans have been diagnosed with AIDS and 120,000 of these have died. Recent statistics released by the Washington, D.C.-based American Psychological Association show that, in the U.S., there are 1.5 million homeless adolescents, approximately 66,000 of whom are HIV-positive.

In Southeast Asia, AIDS is becoming epidemic. In Thailand it is estimated that 6.7 million persons will be infected with AIDS within five years. In India an estimated 1,000,000 are infected. The government is ignoring the epidemic and subsequently chaining people in concentration camps with no treatment at all. The medical community denies the existence of the problem. Similar responses to this epidemic are noted in Russia and Eastern Block countries. Worldwide, the World Health Organization projects 30 million people will test positive for HIV. In America AIDS is the second leading cause of death among men between the ages of 25 and 44; and the fifth leading cause of death among women aged 15 to 44. In the last two years, 1989 and 1990, 55,460 Americans have died of AIDS. This is more than the total of those who died in the first eight years of the epidemic. Deaths are expected to increase from 150% to 350% within the next two years, alone.

In Maryland, 4052 cases of HIV infection have been reported since 1981. The Baltimore metropolitan area reported 2,393 cases through November 30, 1991. Baltimore City alone reported 1,854 cases. The region ranks 16th among metropolitan areas with populations greater than 500,000. The state of Maryland ranks eleventh in AIDS cases nationwide. The Baltimore City Health Department reports that 78 percent of AIDS cases reported are among the Afro-American population. These figures are staggering if you account for the smallness of our state in regards to population and area.

Have we forgotten other health concerns to gather forces to fight just one deadly disease? We hope not, all diseases are harmful to humans and deserve the full attention of researchers and medical care providers to fight them. BUT, HIV + persons have been ostracized or ignored because we have the perception, whether contrived or purposeful, that it is a special disease only contracted by a limited portion of the population. This so called limited "at risk" population is considered the outlaw fringe of society and therefore not worthy of our full attention to treat or alleviate suffering. AIDS is pandemic and affects all of us. Young or old, black or white, rich or poor, homosexual or heterosexual, men or women, adults or children, all are vulnerable.

What has this to do with pharmacists? We don't physically treat these patients, we just dispense the medicines to alleviate their suffering. Did you know that hospital and nursing home pharmacists make IV preparations for AIDS patients? Did you know that in several of our hospitals, pharmacists are directly in contact with HIV positive patient's body fluids, as they start and maintain IV lines as part of the IV service in that hospital; that some of our pharmacies are starting to be involved in home health care for AIDS patients; that some pharmacists in hospitals respond to "Codes" and assist the physician in resuscitating patients?

The PWA (Patient With AIDS) approaches the prescription counter with a handful of prescriptions. The pharmacist or drug clerk scans the prescriptions for completeness and additions of address, etc. The reader notices one Rx is for AZT and the attitude kicks in. Another one of those! We don't want "them" coming into our pharmacy! Have they not enough problems coping with a deadly disease? Does the source of medicines to alleviate their suffering have to be so cold and uncaring? Fortunately, this is not the rule. Several pharmacies in Maryland have made arrangements with charitable care providers to accept assignment for medications and supplies needed for PWA's. This means that the pharmacy carries the credit for the patient until arrangements are made for third party payment. This is program is done through the cooperative efforts of AIDS Action Baltimore and the participating pharmacies.

The neighborhood pharmacist is the source of medications and health advice for their patients. AIDS patients need all the care and compassion we can afford them. Many patients take more than 11 different drugs to treat all the side effects and opportunistic infections they encounter. Imagine their confusion in keeping track of the various administration times and methods of taking these medicines. They are bombarded with all kinds of "helpful" hints to alleviate their suffering. Some are worthless, some are helpful, some just give peace of mind that they are "doing something". We must be informed to help them sort out the fact from fiction, the truth from fraud. We have a moral and professional responsibility to serve all who come to us for medication and medical information. Turning a patient away because we don't want "that kind" in our pharmacies is a disservice to our profession. We are here to treat the sick, regardless of the disease. Remember, in the Middle Ages, the apothecary was one of the few professionals that stayed and treated the plague victims. We have a long tradition of always "being there" when needed by the sick; let's not let that tradition down.

On the research front there are vaccines, antiretrovirals, and various new antibiotics to treat the opportunistic infections so common to the progression of the disease. Hoffman-LaRoche, maker of the anti-AIDS

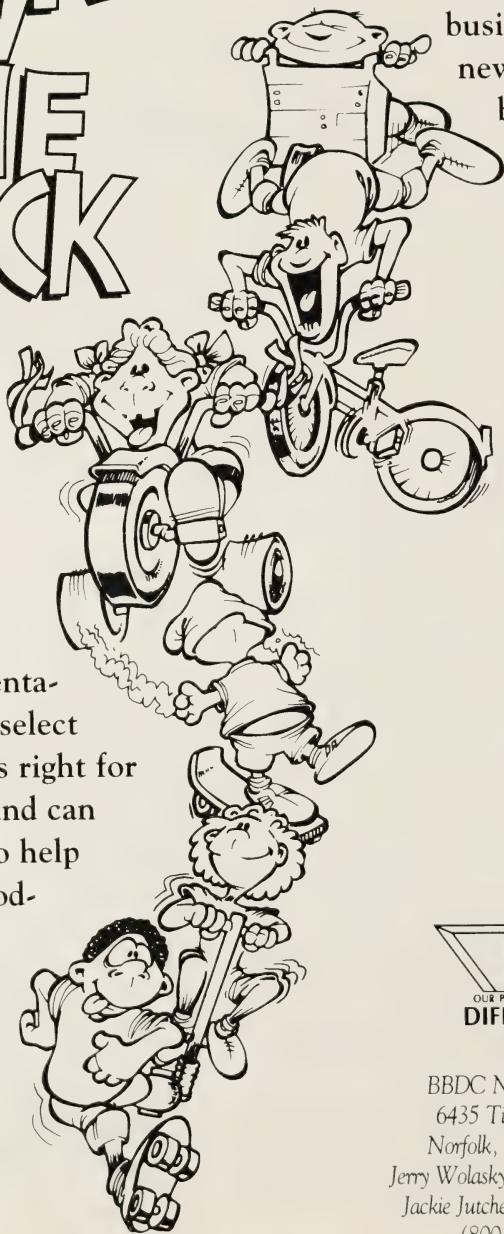
drug ddC, has filed its application with the FDA to market the drug. Assuming relatively rapid response from the FDA, ddC could be in the drugstores by early spring. The political will to approve the drug was ready and waiting as long as a year ago, but developing and filing the application for approval dragged on. Hoffman-LaRoche has one of the best portfolios of experimental AIDS drugs in the world. On November 12th, Burroughs Wellcome announced a limited form of availability (called a Treatment IND) for its new anti-pneumocystis carinii pneumonia (PCP) drug known as 566. It is available, free of charge, to patients with mild to moderate PCP who cannot tolerate or who fail on standard therapy. Patients with severe PCP will also be given the drug under a slightly different program. The main advantage of 566 is lower toxicity than the current therapies, pentamidine and SMZ/TMP.

This month's issue of *The Maryland Pharmacist* is dedicated to information about AIDS. We are presenting all sides of treatments approaches. Mead Johnson Enteral Nutrition Division has generously allowed us to reprint a booklet they publish about nutrition and the AIDS patient. Bristol-Myers-Squibb has provided the latest information for an article describing the use of the AIDS specific antiretroviral, ddI. We have gleaned information from *Facts and Comparisons* and product information supplied by the manufacturers, to round out the details of drug therapy used in AIDS related opportunistic infections. Chris Camp, of the Health Education and Resource Organization (HERO) has supplied us with a list of resource organizations in the state, along with an overview of the status of AIDS in the state of Maryland. We hope you will find the information as enlightening to you as it was to us. Our intent is to condense the material into a usable form for a better understanding of the disease and all of its manifestations. A continuing education quiz based upon the articles may be found on page 30 of this journal. For a more comprehensive overview of AIDS treatments and additional CE credits, please refer to the Glaxo advertisement on page 11 to obtain their book, "Care of the Patient with HIV Infection."

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## Nutritional Care of the Patient with AIDS

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AIDS (Acquired Immune Deficiency Syndrome) is called "Slim Disease" in Africa, a designation that underscores the importance of body wasting in the pathology of this disease.

With AIDS, several factors affect nutrient intake, absorption, and utilization. The disease itself, along with secondary infection, tumors, and medical treatments can alter protein, calorie, vitamin, and mineral nutriture. Although the nutritional consequences of AIDS are recognized, research addressing nutritional issues is still limited. In the meantime, nutritional professionals who care for people with AIDS must refer to the experience of clinicians treating these patients along with insight gained from the management of other chronic diseases.<sup>1</sup>

Mead Johnson Enteral Nutritional recognized the need for a publication which addressed the nutritional issues related to AIDS and set about to compile this data. This monograph is a result of these efforts. The monograph draws upon recently published literature, in addition to the information and opinions shared by a panel of experts in the pathophysiology and care of AIDS patients, who convened in Boston, Massachusetts, in December 1988. The panel included Irwin H. Rosenberg, M.D., Sherwood Gorbach, M.D., and Robert Russell, M.D., from Tufts University in Boston; Charles H. Halsted, M.D., from the University of California at Davis; Donald P. Kotler, M.D., from St. Luke's-Roosevelt Hospital center in New York City; and Barbara Eldridge, R.D., from the Swedish Hospital Tumor Institute in Seattle. Our objective with this monograph is to provide a resource for professionals responsible for nutritional care of adults with AIDS

### Anorexia and Decreased Food Intake

Clinical experience indicates that anorexia and decreased food intake may be primary sources of malnutrition in many patients with AIDS. Loss of appetite can result from the disease manifestations of AIDS or drug therapies, while early satiety is a frequent symptom linked with Kaposi's Sarcoma, gastrointestinal lymphomas, or infection.

**Depression.** Dr. Kotler has found that mild to major depression can be a factor on the anorexia of patients with AIDS. This can occur at any stage of HIV infection. Depression is related to the effects of having a terminal illness. Additional contributing factors may include loss of support from family and friends or financial problems. Depression can be managed with standard psychiatric

treatments: counseling, group therapy, and pharmacotherapy.<sup>16</sup>

**Organic Brain Disease.** Organic brain disease and dementia caused by brain tumors, opportunistic infections, or HIV infection are common in AIDS patients and may also contribute to anorexia and weight loss.<sup>16</sup> Lesions in the hypothalamus have been documented. Dr. Kotler believes anorexia can be related to neurological disease even when intellectual function appears normal. Micronutrient deficiency diseases associated with general malnutrition may also contribute to altered brain and neurological function. Neurological dysfunction can make shopping and meal preparation more difficult and impair self-feeding ability, thereby decreasing food intake.<sup>17</sup> Patients with dementia may simply forget to eat.

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### Symptoms of Depression

Anorexia  
Sleep Disturbances  
Behavioral Changes  
Disheveled Appearance

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**Adrenal Insufficiency.** In some AIDS patients, adrenal insufficiency contributes to anorexia. For these individuals, corticosteroid replacement therapy may help alleviate anorexia and promote weight gain.<sup>16</sup>

**Infection.** Febrile illnesses decrease appetite. Dr. Kotler observed that dietary intake records indicate oral intakes of between 300 and 700 Calories per day during infection. Dyspnea associated with pneumocystis carinii pneumonia (PCP) also affects the patient's ability to eat. In this situation, patients feel they must choose between eating and breathing. Also, fatigue and pain affect the desire to prepare and eat food. As infectious illnesses are treated pharmacologically, food intake may improve.

**Malabsorption.** Patients with malabsorption do not eat sufficiently to compensate for the resulting energy deficit. The presence of unabsorbed nutrients in the lower bowel may suppress appetite, supporting Dr. Kotler's clinical observation that food intake is often greatest early in the day.<sup>18</sup>

**Dysphagia/Dysgeusia.** Infections and tumors affecting the mouth and esophagus can cause ulceration and inflammation. The result may be pain while eating.

Dysphagia, limited salivation, or esophageal obstruction.<sup>1,16,17,19</sup> Neurological disease is another cause of dysphagia.

Medications, such as zidovudine, and infections commonly affect taste. Micronutrient deficiency, particularly of zinc, may also contribute to dysgeusia.<sup>1,16</sup> Other medications that affect taste include Amphotericin B, acyclovir, pentamidine isethionate, and rifabutin.

### Diarrhea and Malabsorption

Diarrhea is often the first gastrointestinal symptom observed in people with AIDS.<sup>21</sup> Patients with diarrhea have greater weight loss and less lean body mass than those without diarrhea.<sup>21</sup> Diarrhea can be due to enteropathies that cause generalized damage and malabsorption in either or both the jejunum and ileum or colonic injury. In many cases, a pathological agent can be identified, though these agents might not be the primary cause of the diarrhea.<sup>19,22</sup> Medical treatments may contribute to diarrhea. Often, however, the cause of diarrhea is not identified.

Medications that may cause diarrhea in AIDS patients include: acyclovir, amphotericin B, diethyldithiocarbamate, cidofovir, nystatin, spiramycin, sulfadiazine, and vinblastine sulfate.<sup>20</sup>

HIV itself may produce gut pathology resulting in intestinal cell atrophy and malabsorption. A number of studies have found HIV in intestinal cells.<sup>23,24</sup> How this relates to intestinal function is not known; but, abnormal gut morphology has been documented in all stages of HIV infection.

Absorption defects have been observed in people during early stages of HIV infection,<sup>24,25</sup> patients with ARC,<sup>23</sup> and clinically stable AIDS patients.<sup>26</sup> Fat, lactose, sucrose, and vitamin B<sub>12</sub> malabsorption are common. Excess fat is frequently detected in the stools of AIDS patients.<sup>26</sup> Many AIDS patients have reduced D-xylose absorption, indicating decreased intestinal absorptive area or intraluminal bacterial metabolism.<sup>26</sup> Fat malabsorption is more common than D-xylose malabsorption, however.<sup>18,23</sup> In addition to fat and D-xylose malabsorption, decreased disaccharidase levels are also common. In one study lactase enzyme activity was undetectable in the duodenum of 60% of HIV-positive patients and others.<sup>24</sup> Lactase activities were decreased in 89% and sucrase activities were decreased in 78 of ARC and AIDS patients in another study.<sup>23</sup> Furthermore, vitamin B<sub>12</sub> absorption (indicated by Schilling tests) was abnormal in eight of 11 AIDS patients who were free of malabsorption symptoms and diarrhea.<sup>27</sup>

Protein malnutrition impairs gut function and causes malabsorption by decreasing pancreatic secretions, intestinal brush border enzymes, and absorptive surface areas.

Diarrhea due to malabsorption is generally characterized by three to 10 bowel movements per day.

### AIDS Medications that May Cause Nausea and Vomiting<sup>14,19,28</sup>

#### Antifungal Agents

Amphotericin B  
Ketoconazole  
Nystatin

#### Antiviral Agents

Acyclovir  
Foscarnet  
Sulfadiazine  
Zidovudine

#### Anti-Cancer Agents

Bleomycin sulfate  
Etoposide  
Vinblastine sulfate

#### Anti-Parasitics

Pentamidine  
Spiramycin

#### Immunomodulators

Methionine encephalane  
Sodium Diethyldithiocarbamate

#### Antibacterials

Ethionamide  
TMP/SMZ

Table 1

Stool volumes are often large and decrease with fasting, yet the patient may feel well and have a reasonably good appetite. In contrast patients with diarrhea due to infectious colitis do not feel well, have poor appetites, and experience multiple bowel movements during the day and night whether they eat or not. This type of diarrhea is commonly caused by cytomegalovirus (CMV), Salmonella, Shigella, Campylobacter, or Clostridium difficile toxin. Severe, chronic, watery diarrhea is often associated with cryptosporidiosis.<sup>19</sup>

### Nausea and Vomiting

Persistent nausea and vomiting may be due the disease itself or complicating diseases. In addition, a number of the medications used to treat the complications of AIDS can cause nausea and/or vomiting. (See Table 1)

### Metabolic Effects of AIDS

The pattern of wasting in AIDS patients consists of increased losses of lean body mass and variable losses of fat.<sup>21</sup> This is not typical of simple starvation in which fat is preferentially used for energy and adaptation of protein metabolism occurs; but, it is similar to the wasting seen in stress conditions such as sepsis or cancer cachexia.<sup>29</sup>

Some infectious conditions are known to result in hypermetabolism. In AIDS patients with Mycobacterium avium-intracellular (MAI), Dr. Kotler reported increased up to 60% in basal energy expenditure.<sup>19</sup> In both AIDS and HIV-positive patients, abnormal fat metabolism has also been documented with 50% for both AIDS and HIV-positive subjects with hypertriglyceridemia.<sup>29</sup> These metabolic effects may be the result of the release of certain cytokines such as interleukin-1, tumor necrosis factor (cachectin), or interferon by immune system cells

due to HIV infection itself, or in response to other infections or tumors.<sup>6,29,30</sup>

Metabolic derangements apparently resist nutritional therapy,<sup>21</sup> but may respond to medical treatment of the underlying disease. Kotler *et al*<sup>31</sup> found that AIDS patients with CMV infection treated with ganciclovir gained weight, repleted body cell mass and body fat, and increased serum albumin concentrations during a 3-month follow-up.

### Nutrition and Immune Functions in AIDS

It is well-known that nutrition affects immunological function; therefore, considerable speculation exists concerning the relationships between AIDS, nutrition, and the immune system. Preventing additional damage to an already compromised immune system is justification for maintaining nutritional status in AIDS patients. Additional speculation has arisen concerning the role of nutrition in HIV infection and its progression to AIDS. At present, however, little scientific data exists and the effects of nutrition on the immunological course of AIDS are not known.<sup>32,33</sup>

The association between protein-energy malnutrition (PEM) and infection has been observed in both malnourished children in under developed countries and hospitalized patients. Protein and energy malnutrition decrease helper T-4 lymphocyte numbers and function, and affect immune function.<sup>32,36</sup> A striking similarity between AIDS and the immunological changes in protein-energy malnutrition has been described.<sup>33</sup>

Other nutrient deficiencies have been related to impaired immune function human or animal models. These nutrients include: Vitamin A, Vitamin B<sub>12</sub>, iron, Vitamin E, thiamin, zinc, selenium, riboflavin, Vitamin B<sub>6</sub>, folate, and Vitamin C.

There is concern that excess levels of nutrients may have negative effects on the immune system. Excess polyunsaturated fatty acids, vitamin A, and zinc can adversely affect immune responses<sup>34,35</sup> and excess free iron may encourage bacterial growth.<sup>36</sup> These observations support the importance of balanced nutrition for normal immune function and oppose nutrient mega-dosing in HIV-infected persons and people with AIDS.

Clinical experience indicates that patients gain weight and lean body mass without increased T-lymphocytes. The effects of nutritional repletion on other components of the body's defenses in AIDS patients is unknown, however. For example, achlorhydria is a common observation in AIDS patients.<sup>37</sup> The role of gastric acidity as a barrier to infection and its interaction with nutrition in persons with AIDS has not been studied.<sup>38</sup>

### Goals of Nutritional Management

The general nutritional goals when caring for the person with HIV infection are to preserve lean body mass, provide adequate amounts for all nutrients, and minimize gastrointestinal symptoms.<sup>1,39</sup> Whenever possible it is important to actively involve the HIV-infected individual when making individual treatment plans.<sup>17</sup> Nutrition counseling should begin when HIV infection is diagnosed and should stress the principles of a balanced diet, regular eating habits, food safety, and ways to modify the diet when complications arise.

Ms. Eldridge finds nutrition is a way HIV-positive individuals can exert some control over their health. The population she works with is very interested in learning about nutrition. In the absence of specific information, these individuals are susceptible to unsubstantiated claims for diets and supplements. They also use a number of unproven dietary therapies such as yeast-free and macrobiotic diets.<sup>40</sup> These dietary treatments have no proven efficacy, may lack important nutrients, and demand additional finances, time, and energy from the patient. Unfortunately, HIV-positive individuals may adopt nutritional therapies as sole therapy for HIV infection instead of effective medical treatment.<sup>40</sup>

When counseling individuals who are using unproven therapies, the health professional need to distinguish between what is harmful, what may be simply ineffective, and what may be helpful from either physical or psychological perspective.<sup>40</sup> A non-judgmental approach, permitting the individual to continue those practices that are neither harmful nor interfere with effective medical therapies, allows the person to maintain control over his or her own care and may help prevent the person from seeking information only from unqualified practitioners.<sup>15,17</sup>

### Nutritional Assessment

A registered dietitian and/or nutrition support team should complete a thorough nutritional assessment of the HIV-infected person. Included in this assessment are several components. (See Table 2)

The nutritional effects of AIDS vary and can change dramatically as the disease progresses. Consequently, nutritional status and the effects of nutritional care should be monitored frequently. Dr. Rosenberg emphasized the importance of conducting nutritional assessments early in the course of the disease, when the person is asymptomatic, thereby establishing baseline information about body composition and nutritional status. Patients receiving nutritional intervention should receive frequent assessments and be checked often for acceptance and tolerance of nutritional modalities.<sup>39</sup>

*Dietary History.* In the dietary history, particular attention should be given to the use of vitamin and mineral supplements and fad dietary regimes.

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### **Nutritional Assessment Components**

Evaluate dietary history  
Measure and assess physical factors  
Assess social, behavioral and economic indices  
Evaluate medical history  
Evaluate weight history  
Consider drug-nutrient interactions  
Evaluate medical therapies  
Assess laboratory values

**Table 2**

Furthermore, it is important to remember that dementia may affect a large number of AIDS patients, and can cause short-term memory afflictions affecting the accuracy of dietary histories.<sup>15</sup>

*Body Composition Assessment.* Body composition evaluations should go beyond taking simple body weight measurements. Kotler et al<sup>21</sup> found that body cell mass depletion, as determined by total body potassium measurements, was greater than that indicated by body weight alone. Several patients with body cell mass depletion had normal or elevated body fat contents. These patients also had increased in total body water and extracellular water that could affect both body weight and blood measurements.<sup>21</sup>

*Biochemical Indices.* A number of biochemical indices are significant in persons with AIDS. But, because of the effects of the disease itself and secondary infections, these indices must be interpreted with caution. Low lymphocyte counts and anergy characterize the disease and are of little value in assessing nutritional status in these patients. Serum albumin may be affected by edema and other factors but is a parameter strongly associated with survival.<sup>41</sup> Other measures may provide additional information about protein status. Kotler et al<sup>21</sup> found that retinol binding protein concentration correlated with total body potassium/height ratios and with iron binding capacity but not with serum albumin concentration. Results of fecal fat analyses, serum carotene measurements, and lactose tolerance tests provide additional information about patients with signs of malabsorption.

### **Nutritional Management**

When choosing nutritional support modalities, consider the individual's medical status, his/he prognosis, time required for repletion, and cost. The gastrointestinal tract is the preferred route of nutrient delivery if its functioning is adequate. Ethical considerations are important factors affecting the decision to provide parenteral nutrition to terminally ill patients.

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## Nutrient Recommendations

**Calories.** Caloric requirements can be estimated using the Harris-Benedict equation and adding allowances for activity, injury, and stress.<sup>1,20</sup> Experience suggests that patients with AIDS or symptomatic HIV-positive patients require about 35 to 40 Calories per kg usual weight to maintain nutrient homeostasis.<sup>39</sup> During recovery from infection it is important to provide enough calories to support protein repletion.<sup>17</sup>

**Protein.** The exact protein needs of AIDS patients with different conditions are not known. The expert panel recommended levels of 1 to 2g per kg per day in symptomatic and metabolically stressed patients. Protein needs can also be estimated using the formula of 1 g of nitrogen per 150 Calories.<sup>20</sup> The nitrogen status of ill patients should be monitored carefully.

**Micronutrients.** Recently, there have been reports of abnormal metabolism of micronutrients in HIV-positive or AIDS subjects. The clinical significance of these observations is not known. They suggest, however, that it would be prudent to recommend balanced (at RDA levels) prophylactic vitamin and mineral supplementation during all stages of HIV infection. Dr. Kotler and Dr. Russell recommend additional minerals such as calcium, magnesium, and zinc in addition to the RDA levels of vitamins, particularly when there is malabsorption.

Many HIV-positive individuals take supplements and need help in choosing appropriate mixtures and amounts. Ms. Eldridge finds that some individuals take up to 100 tablets of different vitamins, minerals, and other dietary supplements per day. Frequently, they are unaware of recommended intake levels, how much they are taking, or possible toxic side effects.<sup>46</sup>

**Dietary Fiber.** Theoretically, dietary fiber degradation could supply short-chain fatty acids in the colon that stimulate sodium and water absorption, acting as an antidiarrheal agent.<sup>48</sup> However, controlled human studies relating enteral liquid diets, with and without fiber, to the incidence or resolution of diarrhea have been lacking.<sup>48</sup> In one AIDS patient, a blenderized, high-residue tube feeding was associated with the resolution of diarrhea, but this patient had no history of diarrhea or malabsorption prior to hospital admission.<sup>49</sup> Dr. Russell and Dr. Kolter find that fiber does not ameliorate diarrhea in AIDS patients. There is also concern that fiber may increase satiety and decrease food intake which is contrary to therapeutic goals. Dietary fiber may be useful, however, in terminal patients who are constipated do to pain medication or as part of normal nutrition in the absence of gastrointestinal complications.

## Management of Symptoms and Conditions

**Anorexia.** Individualized meal plans are especially important to the anorectic patient. Ms. Eldridge increases the number of meals and recommends high-calorie, high-

protein snacks to increase nutrient density. Snacks might include peanut butter, cheese, or commercial supplements. Adding glucose polymers (such as Moducal) to beverages or foods increased calories without adding too much sweetness or volume to the diet.

Pleasant eating situations and companionship also encourage food intake. Since AIDS infection is not spread orally, disposable dishes and utensils are not necessary and providing food on regular dishes rather than disposable dinnerware is more pleasant for most patients.<sup>15</sup>

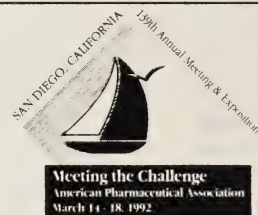
Patients with dyspnea, neurological disease, fatigue, dementia, or depression may need assistance with home meal preparation. Simply prepared foods, convenience items, or meals delivered from agencies may help encourage increase food intake.<sup>15</sup>

Maintaining communication with all members of the health-care team is important since some causes of anorexia are amenable to treatment. For example, adjustments can be made in the timing and dosage of drugs that impair appetite.<sup>16</sup>

If the above measures are not successful, the individual might use a commercial enteral product, such as Sustacal or Sustacal HC, to supplement or replace meals. If oral food intake still does not provide adequate calories and protein, tube feedings may be necessary.

*Dysphagia, Dysgeusia, and Disorders of the Mouth and Esophagus.* Experience with oral and esophageal ailments associated with cancer proves helpful when designing care plans for AIDS patients with similar problems. In

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general, the diet can be modified in consistency, texture, or temperature to maximize oral intake. Good oral hygiene is especially important. If oral or esophageal problems prevent adequate intake, more aggressive feeding modalities may be necessary.

In the presence of lesions, patients generally prefer cool temperatures more than temperatures extremes. Furthermore, they may not tolerate spicy, acidic, or abrasive foods. Nutritionally complete fluids may be easier to swallow and better tolerated by AIDS patients<sup>17</sup> and topical anesthetics may relieve discomfort.

In patients with dysgeusia, appetite may be stimulated with a variety of textures, temperatures, and seasonings. For patients with salivary problems, mealtime liquids, sour candy, or gum might stimulate salivation. The use of gravies, sauces, and dunking dry foods in coffee, tea, or milk can increase the palatability of the diet. Artificial saliva may also be beneficial.

A speech therapist can assist in evaluating patients with difficulty swallowing or aspiration. Patients with swallowing difficulties tolerate thickened liquids or puddings better than thin liquids or solid food.<sup>1</sup> Several of the panel experts have successfully used Sustacal Pudding for these patients. An occupational therapist can provide suggestions if motor ability is impaired due to neurological disease.<sup>17</sup>

**Diarrhea and Malabsorption.** The nutritional management of diarrhea depends upon its severity and the presence of malabsorption. It is important to identify the cause of the diarrhea, if possible, so appropriate medical treatments can be initiated. Patients with diarrhea and malabsorption need individualized nutritional care and careful monitoring because clinical manifestations vary among patients and in the same patient over time.

For most AIDS, patients with mild to moderate diarrhea or malabsorption, the best oral diet is one low in fat, lactose, and caffeine. Patients may be able to consume more food by eating smaller, more frequent meals<sup>1</sup> and may need to supplement their diet with special enteral feedings. In all patients with diarrhea, fluid and electrolyte status is a concern and preventing dehydration is a priority.

**Lactose Intolerance.** Dr. Kotler observed most patients do not tolerate milk, and he recommends the use of lactose-free products. If the patient does tolerate milk, however, it can and should be used since it is a good source of calories and protein. Clinical lactose intolerance, as indicated by symptoms after lactose ingestion, is more important when considering dietary modifications than physiological evidence of lactase deficiency. Clinical tolerance varies considerably among patients and the gut can adapt to lactose, even in the presence of lactase deficiency. Some patients can use milk when Lactaid is added and can tolerate the lactose found in other foods. Others may tolerate only a very low-lactose diet.

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MID-ATLANTIC REGION

**Fat Malabsorption.** Typically, a malnourished AIDS patient cannot tolerate 100-gm fat per day but does tolerate 50-g fat per day, according to Dr. Kotler. Both Dr. Kotler and Ms. Eldridge use lower-fat diets with the addition of lactose-free supplemental feedings such as Sustacal (each 8-ounce serving of Sustacal provides 5.5 g of fat). Dietary fat modifications need to be individualized, however. Dr. Russell points out that some patients with diarrhea do not have fat malabsorption and inappropriate fat restriction removes a valuable flavor enhancer and a concentrated source of calories. Although steatorrhea is an indication of malabsorption, it is not the only factor to consider when modifying fat intake levels. A more important consideration is whether fat malabsorption adversely affects food intake and nutritional status.

MCT (medium-chain triglyceride) oil, more readily absorbed than long-chain triglycerides, may be an alternate source of calories and fat when patients experience fat malabsorption. Dr. Kotler uses MCT Oil as a supplement for low-fat diets. It can be used as a cooking oil and in salad dressings. He finds that many patients tolerate 1 tablespoon 4 times a day (56-gm fat, 460 calories) very well without increasing symptoms. Because it is osmotically active, it should not be taken in large bolus amounts.

Portagen, in which almost 86% of the fat is supplied by MCT oil, has been used successfully by Dr. Kotler for

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pharmacies  
belong to  
Valu-Rite.  
There must  
be a reason.**

**I**n fact, there are lots of reasons. Promotional support for example, especially now that McKesson has added cable TV to their program of circulars and radio spots. Then there's the wide selection of Valu-Rite private label products, and the high profit margins they offer. But most pharmacies probably sign on with Valu-Rite for the same reason I did: it lets me give my customers the personal service they expect from an independent, along with the low prices of a national chain. That's a combination that just can't be beat."

*Scott Richards*

**SCOTT RICKARDS**  
RICKSAVE DRUG  
NAPLES, MAINE

**McKesson**

some patients. Specifically, patients experiencing MAI infection of the jejunum had less diarrhea when they were fed Portagen. Portagen powder can be mixed at 30 Calories per ounce for adult supplementation.

**Predigested Diets.** Elemental formulas have also been used successfully in many AIDS patients.<sup>39,47</sup> To date, however, there are no published studies, demonstrating advantages of using amino acids or predigested proteins rather than complete proteins in AIDS patients. Clinical experiences of the expert panel suggest that the advantage of elemental formulas may be low-fat content. Without evidence of protein maldigestion in patients with AIDS, the rationale for predigested proteins is lacking.

**Hypoalbuminemia.** Since hypoalbuminemia may contribute to diarrhea, serum albumin levels should be monitored and nitrogen intake adjusted appropriately.<sup>1</sup> Serum albumin levels may be increased by nutritional restitution with an elemental enteral formula.<sup>47</sup> Rarely will parenteral administration of albumin be indicated.

**Dehydration.** Severe dehydrating diarrhea or malabsorption requires parenteral therapy with fluids and electrolytes or complete nutrient formulas.<sup>19,20</sup> According to Dr. Kotler, in some cases of severe malabsorption, none of the enteral formulas work. Therefore, parenteral nutrition may be the treatment of choice with consideration given to the patient's prognosis and other factors.<sup>39</sup>

**Nausea and Vomiting.** The dietary management of nausea and vomiting is a process of trial and error.<sup>1</sup> Aggressive enteral (to the small intestine) or parenteral support may be necessary if the intake is inadequate or expected to be inadequate (due to drug treatment, for example) for longer than several days.<sup>1,15,17,20</sup>

### ***Measures to Ameliorate Nausea and Vomiting***

- Avoid greasy, high -fat, strong aroma, very sweet, and spicy foods.
- Offer dry(crackers), cold, or room temperature foods.
- Suggest clear liquids between meals rather than with meals.
- Offer small, frequent meals.
- Provide a relaxed eating atmosphere.
- Instruct the patient to avoid the kitchen during meal preparation if cooking aromas are nauseating.
- Consider treating with anti-emetic drugs.
- Alter dosage and timing of drugs which cause nausea.
- Alter timing of meals if nausea occurs at specific times.

## **Food Safety**

People with Aids need counseling about food safety since they are more susceptible to infection by food-borne organisms such as Salmonella and can develop life-threatening bacteremia from these infections.<sup>38,50</sup> While food safety is important, no evidence exists supporting very restricted, sterile, or "low-bacteria" diets for these individuals and there are considerable practical disadvantages of such a diet.<sup>51</sup>

### ***Food Safety Precautions***

- Store perishable foods in refrigerator or freezer immediately after purchase.
- Thaw meat, fish, or poultry in the refrigerator.
- Thoroughly wash hands before food preparation and after handling raw meats, fish, or poultry.
- Use separate cutting boards, plates, and utensils for raw and cooked meats, fish, or poultry.
- Thoroughly cook meats, fish, and poultry.
- Avoid using raw, unpasteurized eggs in uncooked foods.
- Purchase only clean, whole eggs.
- Discard cracked or dirty eggs.
- Purchase only pasteurized milk.
- Remember that bacteria grow best between 40°F and 140°F.

### **Efficacy of Nutritional Support**

Observations suggest that nutritional support improves the quality of life and overall health. It does not, however, have an impact on the basic disease process nor increases T-lymphocytes in patients with AIDS. Dr. Kotler reminds us that, "Nutrition is not the sole therapy of anything except malnutrition, and nutrition is not the only factor in the response of a patient with AIDS." When lean body mass is restored, however, patient may be able to leave their beds and live more active lives.

Dr. Kotler reported results of a study of malnourished patients who were able to leave the hospital following nutritional rehabilitation. The patients had no severe, active complications and had adequate absorptive capacity based on D-xylose absorption. Most of these patients gained significant amounts of weight with repletion of lean body mass with gastrostomy tube feedings. These

results demonstrate the cost-effectiveness of nutritional support in certain AIDS patients.

It has also been Dr. Kotler's experience that patients without systemic infections respond to aggressive nutritional support with lean body mass repletion.<sup>52</sup> In contrast, patients with systemic disease, such as disseminated CMV or MSI infections, respond less to nutrition support and may fail to achieve rehabilitation.<sup>19</sup>

### Future Trends

The number of homosexual and bisexual men with AIDS may level off because of changes in sexual behavior.<sup>53</sup> Since blood and plasma are now screened for HIV infection and clotting factors are now heat-treated, the numbers of individuals infected by blood transfusions or through administration of blood components will also continue to decrease. The CDC statistics indicate a trend toward a decreasing proportion of homosexual or bisexual male AIDS patients and an increasing proportion of patients with a history of IV-drug abuse.<sup>12,13</sup>

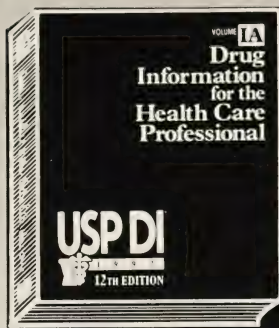
The proportion of women with AIDS is also rising.<sup>13</sup> Among these women, 52% had histories of IV-drug abuse and 25% had sexual partners with HIV infection or known risks for HIV infection. As the number of IV-drug abusers with AIDS will also increase since perinatal infection appears to be the primary route of transmission for children. The incidence of AIDS is highest in large metropolitan areas of the mid-Atlantic region and West Coast. However, the disease is spreading to other areas of the country. AIDS has been reported in all 50 states.<sup>13</sup>

These statistics imply that more health practitioners will be taking a role in the care of AIDS patients in the next several decades. Also, as the characteristics of AIDS patients change, the costs of medical care to the public will increase dramatically, since many IV-drug abusers and their families are indigent.

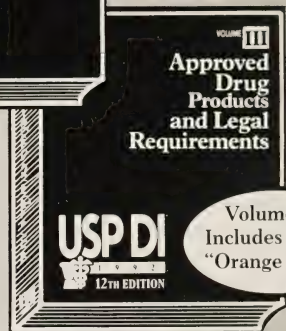
The demographics of people with AIDS affect nutritional care. Clinical experience suggests that many HIV-infected persons comply with therapy and accept nutritional advice. Intravenous drug abusers, however, tend to be less compliant with any form of treatment. Working with social and economic factors affecting the nutritional status of drug abusers is an additional challenge for nutritionists.

Many questions remain regarding the nutritional care of people with AIDS and the role of nutrition in the etiology of the disease. Dietitians and nutritionists must take a leadership role in addressing these issues and in documenting the efficacy of various types of nutritional care at different stages of the disease. Considering the nutritional ramifications of this disease, registered dietitians play an essential role in the health-care team and must actively participate in the management of HIV-infected individuals from the time these individuals are first determined to be seropositive. ■

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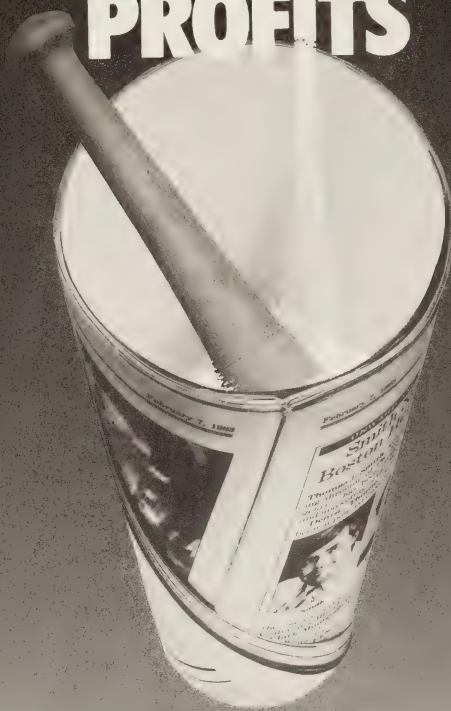
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# Nutritional Care of the Patient with AIDS

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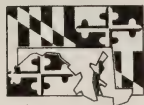
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## Drug Therapy for AIDS Complications

Randy Delker, Pharmacy Student

University of Maryland School of Pharmacy

Pharmaceutical therapy for patients with AIDS is not limited to antivirals. The combat of the HIV virus itself is only a portion of AIDS disease treatment. The many illnesses arising from a compromised immune system require aggressive and complicated regimens.

This article will review the many drugs currently being used to treat the concomitant diseases associated with AIDS.

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### Interferon

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*Interferon/Roferon Interferon alfa-2a, recombinant (Roferon-A - Roche)* became available in November 1988 for the treatment of the AIDS related cancer, Kaposi's sarcoma. K.S. typically causes reddish-purple or brown skin lesions which may be disfiguring and may progress to involve the lymph nodes and internal organs and can be fatal if present in the lungs. Available as an injectable solution that is given daily for 10-12 weeks and administered either SC or IM, Roferon-A response depends on the manifestations of HIV infection but not to the extent of tumor involvement.

Pharmacists should advise patients who intend to undergo Interferon therapy that proper hydration during initial therapy is important and that changing of brands of Interferon is not recommended due to the possibility of changing of dosing. Subcutaneous administration is suggested for patients who are at risk for bleeding or who are thrombocytopenic (platelet counts  $<50,000/\text{mm}^3$ ). When disease progression is halted or response to

therapy occurs, treatment should continue until there is no further evidence of tumor or adverse effects occur. There is no optimal duration of treatment. Dosing is normally 36 million IU daily for 10-12 weeks and then a maintenance dose of 3 million IU three times a week. The apparent fraction of the drug that is absorbed after an IM injection is 80%.

Interferon is metabolized by proteolytic degradation during tubular reabsorption. Liver and biliary excretion are of little significance to elimination.

Adverse effects normally observed with the use of Interferon are: flu-like symptoms (fever, fatigue, headache and chills), nausea, diarrhea, abdominal pain, dizziness, depression, mental confusion, coughing, rash, weight loss, change in taste and dyspnea. Other adverse effects were noted in patients with other underlying disease states and are individualized for such patients. The only noted drug interaction to date is a reduction in the clearance of aminophylline due to inhibition of the cytochrome P450 enzyme system.

Reduction in the dosage or withholding individual doses may be necessary to manage adverse effects. Roferon-A may be used in the outpatient setting or home administration and includes detailed instructions for the patients use. Clinical studies have shown that in HIV infected patients with Kaposi's sarcoma, treatment with Roferon-A has shown both tumor regression and prolongation of survival in 45% of those treated.

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### Erythropoietin

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*Epoen (Epoetin Alfa; Erythropoietin)* Erythropoietin is a glycoprotein which stimulates red blood cell production. It is produced in the kidney and stimulates the division and differentiation of erythroid progenitors in the bone marrow. Epoetin Alfa is manufactured by recombinant DNA technology.

Adverse reactions include fever, fatigue, headache, cough, diarrhea, rash, nausea, asthenia, skin reaction at injection site and dizziness.

Dosage in HIV infected individuals starts at 100 Units/kg SQ 3 times weekly for 8 weeks. If a satisfactory response is not obtained, the dose is increased in increments to up to 300 Units/kg 3 times weekly. A maintenance dose is then titrated to reflect response and conditions produced by the ongoing HIV infection.

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### Neupogen

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*Neupogen (Filgrastim; Granulocyte Colony Stimulating Factor; G-CSF)* Filgrastim is a colony stimulating factor produced by recombinant DNA technology. Human granulocyte colony stimulating factor are glycoproteins which act on hematopoietic cells by binding to specific cell surface receptors and stimulating proliferation, differentiation commitment and some end-cell functional activation. G-CSF primarily affects neutrophil progenitor proliferation, differentiation and

selected end-cell functional activation.

The most common adverse effects are nausea and vomiting, skeletal pain, alopecia, diarrhea, and fever.

There is no maximum dose of filgrastim determined. The recommended starting dose is 5mcg/kg/day, administered SQ daily. Subsequent doses are adjusted according to response as determined from ANC level. This drug is given in response to the discernable symptoms of the ongoing HIV infection.

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### *Leukine*

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*Prokine, Leukine (Sargamostim; Granulocyte Macrophage Colony Stimulating Factor; GM-CSF)*

Sargamostim is a recombinant human granulocyte-macrophage stimulating factor produced by recombinant DNA technology. GM-CSF is a hematopoietic growth factor which stimulates proliferation and differentiation of hematopoietic progenitor cells. GM-CSF can also activate mature granulocytes and macrophages. GM-CSF is used to increase white blood cell counts patients receiving Zidovudine.

The only drug interactions noted are with Lithium and Corticosteroids. These drugs may reduce the myeloproliferative effects of GM-CSF.

Adverse reactions include fever, mucous membrane disorder, asthenia, malaise, edema, nausea, diarrhea, vomiting, anorexia, alopecia, rash, dyspnea, lung disorder, blood dyscrasia, and hemorrhage. The drug may aggravate preexisting fluid retention.

The maximum dose has not been determined. 250 mcg/m<sup>2</sup>/day for 21 days as a 2 hour IV infusion has been used for bone marrow transplantation. Sargamostim contains no preservative, therefore it must be refrigerated and used within 6 hours of reconstitution.

*Pentamidine Isethionate (NebuPent - Lypomed)* for inhalation is presently

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### *Pentamidine*

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being used in HIV infected patients for the treatment of and prevention of *Pneumocystis Carinii* Pneumonia (PCP). Use for prevention is indicated when the patient has either has a history of one or more episodes of PCP or a peripheral CD4 count less than or equal to 200/mm<sup>3</sup>. Oral inhalation therapy of 300mg is given every four weeks administered via the Respigard II nebulizer. The aerosol treatment is given over a 30-45 minutes period or until the nebulizer chamber is empty. (For those patients that can not tolerate 300mg each month, doses of 150mg every two weeks have been used and tolerated well).

Precautions that the pharmacist should mention to HIV infected patient receiving pentamidine are three fold. First, if the patient is using a bronchodilator inhaler, it should be used 5-10 minutes prior to the pentamidine treatment. Second, a possible bitter or metallic taste may develop after administration of pentamidine and the use of hard candy after treatment may reduce this effect. Third, cigarette smokers may experience coughing and bronchospasm during therapy.

Typical adverse effects seen with the use of pentamidine include: chest pain, congestion, dyspnea, dryness, difficulty swallowing, skin rash and wheezing. Pancreatitis and renal insufficiency occur very rarely and normally only after daily treatment. Systemic absorption is minimal. In asthma patients, pentamidine may induce bronchospasm and this may be reduced with pretreatment with a bronchodilator (albuterol, metaproterenol or terbutaline) and the use of a nebulizer that produces a small particle size.

There is a low incidence of severe side effects with the prophylactic use of aerosolized pentamidine. Most of the adverse effects will be due to other causes, such as, other

medications, other infections and/or the HIV infection. A number of cases of extrapulmonary pneumocytosis (pneumocytosis infection outside the lungs) have been reported in patients receiving aerosolized pentamidine. It appears to occur more often in patients diagnosed with AIDS for greater than 12 months who usually have previous bouts of PCP, concurrent use of zidovudine (Retrovir - Burroughs-Wellcome), and have had prolonged use of pentamidine.

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### *Foscavir*

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*Foscavir sodium (Foscavir - Astra)* for the therapy to delay progression of cytomegalovirus (CMV) retinitis, that occurs in 20% of AIDS patients and often leads to blindness became available for prescription in October 1991. While most people carry the virus, only those who are immunosuppressed express CMV infection and half of those infected with CMV will go blind within four months. Available by intravenous treatment, Foscavir is not a cure for CMV retinitis and patients may continue to experience progression of retinitis either during or after treatment.

Dosing for Foscavir is currently 60mg/kg every eight hours for the first two to three weeks, followed by maintenance therapy at 90-120 mg/kg per day. If progression of retinitis occurs, higher doses may be given. However, all doses must be individualized for patient's renal function. Foscavir is excreted unchanged in the urine of patients with normal renal function and may undergo tubular reabsorption. Mineral and electrolyte abnormalities have been associated with Foscavir including: hypocalcemia, hypo and hyperphosphatemia, hypomagnesemia and hypokalemia and such changes may increase the patient's risk for cardiac disturbances and seizures. Therefore it should be stressed that proper monitoring (including lab

work) should be followed as instructed for optimal therapy and reduction of adverse effects.

The most frequently reported events following administration of Foscavir were: fever, nausea, anemia, diarrhea, abnormal renal function, vomiting, increased serum creatinine (decreased creatinine clearance), headache and seizures. Many HIV infected patients receive pentamidine (PCP prophylaxis) and Foscavir may interact. In one study with concomitant treatment, hypocalcemia was observed and one death was attributed to hypocalcemia. However, toxicity with aerosolized pentamidine has not been reported. Potential renal impairment may be minimized by proper hydration to establish and maintain a diuresis during dosing.

Most important for the pharmacist is preparing Foscavir for injection, care must be taken to ensure that Foscavir is only administered with normal saline or 5% dextrose solution and that no other drug or supplements are administered concurrently via the same catheter.

### Fluconazole

*Fluconazole (Diflucan - Roerig)* is an antifungal currently being used in HIV patients showing symptoms of esophageal or oropharyngeal candidiasis, commonly termed thrush. While this condition is seen in children, the symptoms and severity is much greater in the HIV infected patient. Thrush most commonly presents as white patches of the oropharynx and raised plaques throughout the esophagus, that may impair swallowing and eating. Pain may be intense for the patient and local anesthetics may have to be used to accommodate eating. Recurrent infections typically seen in HIV infected patients may require maintenance therapy to prevent relapse.

Available as both an oral tablet (50mg, 100mg and 200mg) and an intravenous injection (200mg/100ml


and 400mg/200ml), bioavailability between the two products are almost identical with the oral tablets being >90% absorbed as compared to the injection. Serum peak concentrations occurs 1-2 hours after oral administration and fluconazole is primarily cleared by renal excretion. Doses should be adjusted for renal insufficiency or renal failure. Dosing is initiated at 200mg on the first day followed by 100mg once daily. Symptoms of infection usual reside within several days. However treatment should be continued for at least 2-3 weeks after clinical findings have cleared. Doses as high as 400mg per day have been used in severe cases of infection. Significant drug interactions have been reported with the use of fluconazole. Concurrent use of oral antidiabetic agents (tolbutamide, glyburide and glipizide) have increased the concentrations of these hypoglycemics. Blood glucose levels should be monitored and the dose of the hypoglycemic may be reduced if necessary. Co-administration with warfarin results in increased prothrombin time (PT). Use of fluconazole and phenytoin may decrease the metabolism of phenytoin, therefore levels should be carefully followed. Concurrent use with rifampin may increase the metabolism of fluconazole and result in the need to increase the dose of fluconazole.

Adverse effects typically presented with the use of fluconazole have been reported more frequently in the HIV infected patient than in the non infected patient. Headache, GI discomfort, nausea, vomiting and diarrhea are the most bothersome for the patient. rarely, exfoliative skin disorders, including Stevens-Johnson syndromes (reddening, blistering, peeling or loosening of skin and mucous membranes) have occurred. Hepatotoxicity is rare, but may manifest itself as dark urine, yellow skin or eyes, pain or tenderness on right side under ribs or anorexia. ■

*Resources used in the preparation of this article include Facts & Comparisons, USP/DI, and product package inserts.*

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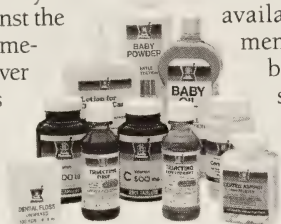
<sup>1</sup> FDA survey, "Patient Receipt of Rx Drug Information", 1983

<sup>2</sup> A Study of Attitudes, Concerns, and Information Needs for Rx Drugs and Related Illnesses, CBS Television Network Consumer Model Survey, 1983

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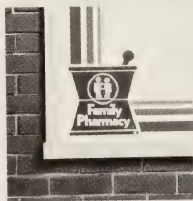
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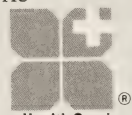
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## Antiviral Therapy of AIDS

Randy Delker, Pharmacy Student  
University of Maryland School of Pharmacy

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### Zidovudine/AZT

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Zidovudine (AZT/Retrovir - Burroughs-Wellcome) is probably the best known antiretroviral agent known to pharmacists today. Available as 100mg capsules, strawberry flavored syrup (50 mg/5 ml) and single use injection (10mg/ml), Retrovir is the most frequently used drug in the treatment of AIDS and ARC. As the health care provider, the pharmacist should inform the patient of certain data. First, zidovudine is not a cure for HIV infection and patients may still acquire illnesses and opportunistic infections and should seek health care if a change in their health status occurs. Second, the use of zidovudine does not reduce the risk of transmission of the HIV virus either through sexual contact or blood contamination.

As for the pharmacist, the information needed to provide complete health care is numerous. Zidovudine therapy is initially started in HIV infected patients with CD4 cell counts less than or equal to  $500/\text{mm}^3$ , for adults and for children aged three months or older who have HIV-related symptoms or indications of severe immunosuppression. Dosing is dependent on symptoms. If the patient is asymptomatic, then dosing is typically 100 mg every four hours while awake (500 mg/day) and 200 mg every four hours around the clock if symptomatic. Blood monitoring must be done for anemia or granulocytopenia and the dosing must be adjusted as necessary. Zidovudine is rapidly absorbed from the GI tract and peak blood levels occur within 0.5 to 1.5 hours. Absorption of the syrup is greater than that of the capsules. Zidovudine is metabolized in the liver to an inactive metabolite and dosing adjustments should be made for those patients with renal failure.

Typically seen adverse effects with the administration of Zidovudine include: anemia, granulocytopenia, headache, nausea, insomnia, GI pain, rash and taste perversion. Drug interactions are seen with Zidovudine and acetaminophen which may increase the risk of granulocytopenia. Co-administration of Zidovudine and other drugs that may be nephrotoxic or cytotoxic (dapsone, pentamidine, amphotericin B, flucytosine, vincristine, adriamycin or interferon) may increase the risk of toxicity. Probenecid may inhibit or reduce the renal excretion of zidovudine. While these are not all the

possible drug interactions and adverse effects, they do represent the major effects seen, however, any unusual effect and co-administration of other medications should be monitored carefully and followed up thoroughly.

The rationale for early intervention with zidovudine is clear. First, it is known that the viral burden increases with time and early on plasma levels of virus may be low and the number of infected cells may be small. Therefore, the early use of antiretroviral agents may well prevent a larger number of cells from becoming infected. Also, intervention to suppress HIV infections while the immune system is still intact may help stabilize or slow additional damage to the immune system and its functions. Moreover, looking at long-term follow up of patients, there is no evidence of loss of efficacy of zidovudine. There appears to be continued long-term benefit. Benefits are shown to all patients with a CD4 cell count below  $500/\text{mm}^3$  and early initiation is associated with better tolerance. Therefore, the early treatment of HIV infection with Zidovudine shows an inhibition of HIV reverse transcriptase and prevents a larger number of cells from becoming infected.

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### Didanosine/ddI

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Didanosine (ddi, Videx - Bristol Myers Squibb), a nucleoside analogue of deoxyadenosine, is an inhibitor of the in vitro replication of HIV (also known as HTLV III or LAV) in human primary cell cultures and in established cell lines. After ddI enters the cell, it is converted by cellular enzymes to the active antiviral metabolite, dideoxyadenosine triphosphate (ddATP). The intracellular half-life of ddap, calculated from results obtained from in vitro culture studies, varied from 8 to 24 hours. Didanosine is indicated for the treatment of adult and pediatric patients (over 6 months of age) with advanced HIV infection who are intolerant of zidovudine therapy or who have demonstrated significant clinical or immunologic deterioration during zidovudine therapy. *At present there are no results from controlled studies regarding the effect of ddI therapy on the clinical progression of HIV infection, such as incidence of opportunistic infections and survival.* Because zidovudine has been shown to prolong survival and decrease the incidence of opportunistic infections in patients with advanced HIV

disease, zidovudine should be considered as initial therapy for the treatment of advanced HIV infection, unless contraindicated.

A common feature of dideoxynucleosides (the class of compounds to which ddI belongs) is the lack of a free 3'-hydroxyl group. In nucleic acid replication, the 3'-hydroxyl of a naturally occurring nucleoside is the acceptor for covalent attachment of subsequent nucleoside 5'-monophosphates; its presence is therefore requisite for continued DNA chain extension. Because ddATP lacks a 3'-hydroxyl group, incorporation of ddATP into viral DNA leads to chain termination and, thus, inhibition of viral replication. In addition, ddATP further contributes to inhibition of viral replication through interference with the HIV-RNA dependant DNA polymerase (reverse transcriptase) by competing with the natural nucleoside triphosphate, dATP, for binding to the active site of the enzyme.

Clinically significant ddI resistance in patients with HIV infection after receiving ddI therapy has not been studied adequately and the frequency of ddI-resistant isolates in the general population remains unknown. The results of cytotoxicity studies in various cell lines have shown little cytotoxic action with ddI. ddI has shown antiviral activity in one mouse animal model. It has been shown that antiretroviral agents can prevent development of HIV viremia in this animal model system. Didanosine has been shown to inhibit human hepatitis B virus (HBV) replication *in vitro*. The clinical significance of these findings is unknown.

The major toxicities of ddI are pancreatitis and peripheral neuropathy. In addition, studies have also reported liver disorders and retinal disturbances from ddI therapy. Additional adverse reactions and their incidences are listed in Table 1.

Pancreatitis occurred in 9% of patients in phase 1 studies treated with ddI at or below the recommended dose. This condition can be fatal. Pancreatitis must be considered whenever a patient receiving ddI develops abdominal pain and nausea, vomiting, or elevated biochemical markers. Under these circumstances, ddI use should be suspended until the diagnosis of pancreatitis is excluded. When treatment with other drugs known to cause pancreatic toxicity is required (for example, IV pentamidine), suspension of ddI should be considered. Patients with renal impairment may be at greater risk for pancreatitis if treated without dose adjustment. Patients with a history of pancreatitis should be followed more closely, as should those with other risk factors such as those with alcohol consumption and elevated triglycerides.

Peripheral neuropathy occurred in 34% of patients in phase 1 studies treated with ddI doses at or below the currently recommended dose. Patients should be

### *Didanosine Adverse Reactions*

	Phase 1 12.5 mg/kg N=91	Phase 1 All Patients N=170	U.S. Expanded Access N=7806
Headache	36%	32%	5%
Diarrhea	34%	29%	18%
Peripheral Neuropathy	34%	42%	16%
Asthenia	25%	24%	3%
Insomnia	25%	22%	2%
Nausea/Vomiting	25%	25%	8%
Rash/Pruritus	24%	25%	4%
Abdominal Pain	21%	22%	5%
CNS Depression	19%	16%	<1%
Constipation	16%	13%	<1%
Stomatitis	14%	11%	<1%
Myalgia	13%	13%	1%
Arthritis	11%	11%	1%
Taste Loss/Perversion	10%	8%	<1%
Pain	10%	16%	4%
Dry Mouth	9%	8%	1%
Pancreatitis	9%	17%	5%
Alopecia	8%	7%	<1%
Dizziness	7%	8%	1%

**Table 1**

monitored for the development of a neuropathy that is usually characterized by distal numbness, tingling, or pain in the feet or hands. Many patients tolerated a reduced dose of ddI. Neuropathy occurred more frequently in patients with a history of neuropathy or neurotoxic drug therapy. These patients may be at increased risk for neuropathy during ddI therapy.

Liver failure of unknown etiology has occurred in less than 0.2% of patients receiving ddI.

Four pediatric patients demonstrated retinal depigmentation at doses of ddI above 300mg/m<sup>2</sup>/day. Until further information is available, children receiving ddI should undergo dilated retinal examination every 6 months or if vision occurs.

Because food can reduce the absorption of ddI by as much as 50%, it should only be taken on an EMPTY stomach. The chewable tablets do contain phenylalanine. Patients with sodium restricted diets may want to be aware that the sodium content of the tablets (2 tablet dose) equals 264.5 mg. and each packet of powder for oral solution equals 1380 mg. Renal impairment may mean that a downward adjustment in dose is indicated to avoid toxicity due to reduced excretion. Similarly, hepatic impairment may necessitate dosage reductions. Some diarrhea has been noted. This may be attributed to the antacid content of the dosage forms. But no hard data is available at this time to substantiate this. This appears to be more of a problem with the oral solution rather than the tablets.

Just as with AZT, ddI is not a cure for HIV infection, and patients may continue to acquire illnesses associated with AIDS or ARC, including opportunistic infection. The frequency of these infections has not been shown to be reduced by administration of ddI. The major toxicities of ddI are pancreatitis, which could be fatal and peripheral neuropathy. Alcohol consumption may exacerbate toxicities of ddI. Transmission of HIV to others is not reduced by using this drug. Sexual contact and blood contamination are still precautions to keep in mind to prevent transmission.

Drugs whose absorption can be affected by the level of acidity in the stomach (eg, ketoconazole, dapsone), should be administered at least 2 hours prior to dosing with ddI. Coadministration of ddI with drugs that are known to cause peripheral neuropathy or pancreatitis may increase the risk of these toxicities. Patients who receive these drugs should be observed closely. A study of 4 patients revealed that concomitant administration of ganciclovir does not significantly affect the pharmacokinetics of ddI. There is evidence that ddI potentiates the myelosuppressive effects of ganciclovir.

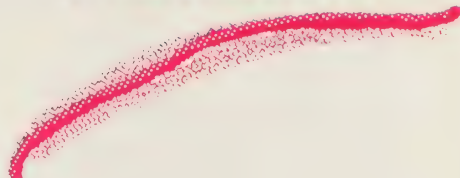
As with other products containing magnesium and/or aluminum components, Videx Chewable /Dispersible Buffered Tablets or Videx Pediatric Powder for Oral Solution should not be administered with a prescription antibiotic containing any form of tetracycline.

Plasma concentrations of some quinolone antibiotics are decreased when administered with antacids containing magnesium and aluminum. Therefore, doses of quinolone antibiotics should not be administered within 2 hours of taking ddI oral preparations. Concomitant administration of antacids containing magnesium or aluminum with ddI oral preparations may potentiate adverse effects associated with the antacid components.

The dosing interval should be 12 hours. All ddI (didanosine) formulations should be administered on an empty stomach. Adult patients should take 2 tablets at each dose so that adequate buffering is provided to prevent gastric acid degradation of ddI. ■

*Data for this article was obtained from Facts & Comparisons, USP/DI and product package inserts.*

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# District Photo's

## Product and Promotions Page



SmithKline Beecham has announced the release of Relafen (nabumetone), a non-steroidal anti-inflammatory drug demonstrated to have efficacy comparable to other NSAIDs with a low risk for upper gastrointestinal irritation. Relafen is designed for once daily dosing.



Nutrina, a company specializing in food supplements, has announced their latest product, SMART. Touted as a part of a "Swedish Weight Loss System," the new product will be promoted with a national ad campaign.



Merck & Company have announced the introduction of Zocor (simvastatin), a new antilipidemic designed to combat patients with high low-density lipoprotein levels.



Scripto has announced a special promotion, including \$10,000 college scholarship, as well as millions of other prizes, to help sell their pen sets.

### DISTRICT PHOTO

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# Important figures in diabetes care



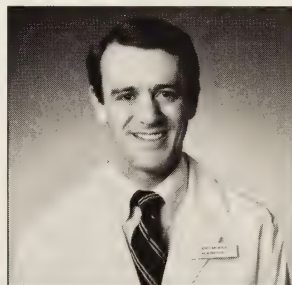
Diabetes is the **No. 7** cause  
of death in the US<sup>1</sup>

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Diabetes is the **No. 1** cause of new  
blindness in persons aged 20-74<sup>1</sup>

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without diabetes.<sup>2</sup>

---



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1. *Diabetes Surveillance, 1980-1987*. Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes*. Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

## AIDS Resources for Maryland

*Christopher Camp, Development Associate  
Health Education Resource Organization, Inc. (HERO)*

That the AIDS epidemic has reached crisis proportions in Maryland is no surprise to most health care providers. Since 1989, AIDS-related disease has become the leading cause of death for Central Maryland's young adults of all racial backgrounds, ages 25 - 44. Listed as 10th in the total cumulative cases of AIDS in the U.S. since 1981, Maryland's rank becomes all the more frightening when considered in relation to its total population (Maryland is ranked 19th) and geographic area (Maryland is ranked 42nd).

How well are we responding to the dramatic challenges of which we face? Where and who is being overlooked? The following presentation is an overview of AIDS/HIV education and services currently provided in Maryland. This report is example-based, and not intended as a comprehensive picture. After the overview presentation, steps of action will be proposed. Much thanks go to the Division of Public Education Center for AIDS Education in the Maryland State AIDS Administration.

The World Health Organization's Global Program on AIDS has proposed the following steps of action:

- Existing AIDS programs must be consolidated. To insure capability in the coming decade, stronger linkages must be forged with other health and social programs. More attention must be paid to program staff and staff development, and the capability for management planning, and evaluation must be improved.
- Programs need to identify specific areas which merit focus and strengthening. In every community, AIDS has inevitably highlighted certain pre-existing and complex health and social problems.
- AIDS programs must continue to innovate, for some of the challenges which AIDS presents to individuals and society will require new approaches - for prevention, for care, and to assure equity in the provision of health and human services, including therapeutic agents and, eventually, a vaccine. AIDS programs must not stop challenging the status quo - especially when the status quo is simple not good enough.

There is no precedent in the history of public health efforts for the speed, intensity, or scope of this global mobilization against AIDS. This in itself is cause for

optimism. However, the control and ultimate prevention of AIDS will require sustained, long-term national and international commitment. There will be no easy answers.

### Private Organizations

- Planned Parenthood* (301) 261-1182/(410) 269-1020  
Targets sexually active teenage women, ages 13 to 17, African-American, at a low socio-economic level.
- Health Care for the Homeless* (410) 837-5533  
Targets long-term and temporarily homeless persons, through a "train-the-trainer" approach undertaken with staff at shelters and soup kitchens.
- Man Alive* (410) 837-4292  
Peer educator program targeted to their methadone maintenance clients.
- H.E.R.O.* (410) 685-1180  
Street outreach program (Y.A.A.P.P. - Young Adults AIDS Prevention Project) targeting adolescents and young adults, ages 13 - 21, in the IVUDU and prostitution subcultures of southwest Baltimore City.
- Baltimore Urban League* (410) 576-0201  
Peer educator risk reduction program for teen mothers and their peers.
- Whitman-Walker* (202) 797-3500  
Provides HIV/AIDS information and condoms in some area bookstores.
- SALUD* (202) 483-6806  
Outreach to hispanic communities in Montgomery and Prince George's Counties.
- Sexual Minority Youth Assistance League* (202) 546-5940  
Outreach to sexual minority youth.
- GLCC of Baltimore* (410) 837-5445  
Outreach to sexual minority youth.
- Bogan Associates* (301) 588-0132  
Church-based education for the adult minority population.
- Street Voice* (410) 243-3921  
Outreach for IV drug users and the homeless.

- C. Whitney Institute* (410) 637-5432  
Outreach to African-American families.
- Health and Welfare Council* (410) 752-4146  
Community-level prevention via the "Stop AIDS" campaign.
- AIDS Action Baltimore* (410) 837-2437
- AIDS Alliance of Howard County* (410) 461-5530
- AIDS Interfaith Network* (410) 728-5545
- AIDS Partnership Council* (410) 324-9409 or 938-3521
- Deaf AIDS Project/Family Services Foun.* (410) 752-1589
- Chase-Brexton Clinic* (410) 837-2050
- PWA Coalition of Baltimore* (410) 625-1677
- American Red Cross, Central Maryland* (410) 764-7000
- Morris Goldseker Foundation of Maryland*

### **Maryland State Agency Programs**

- Alcohol and Drug Abuse Administration* (410) 225-6925  
Provides literature and condoms at treatment centers, provides HIV risk assessment within first 30 days of intake; the Office of Education and Training provides many AIDS-related courses to substance abuse treatment professionals
- Developmental Disabilities Administration* (410) 225-5600  
Provides AIDS updates upon request to field staff, Develops AIDS updates for central office staff, and offers AIDS prevention messages to clients where appropriate.
- Mental Health Administration* (410) 225-6707  
Recently completed "train-the-trainer" program to provide staff with seminars/workshops. Twelve different facilities provide materials and information to staff and clients as needed.
- Local and Family Health Administration* (410) 225-5600  
Counseling and testing sites are operated at each local health department. Prevention materials, speakers, workshops and seminars are offered. Prevention counseling is offered in STD, TB, family planning, mental health, and substance abuse programs. Regional AIDS Educators within local health departments provide prevention services to local schools, businesses, and organizations.
- Laboratories Administration* (410) 225-6155  
Provides patient information materials to private providers who are sent back HIV antibody-positive test results.
- Licensing and Certification* (410) 764-2750  
Provides prevention education to staff.
- Division of Correction* (410) 764-4400  
Provides training seminars to correctional officers regarding occupational risk; provides literature and condoms to inmates being released or going on family leave; provides prevention workshop upon intake.

- Department of Human Resources* (410) 333-0011  
Provides mailing inserts to public assistance recipients statewide. DHR central office staff and child care providers are trained by AIDS Administration staff.

- Department of Juvenile Services* (410) 333-6777  
Staff is provided with training by AIDS Administration. AIDS information is displayed on bulletin boards, and prevention literature is provided to clients and staff upon request.

- Maryland State Department of Education* (410) 333-2200  
Administers funds to provide teachers in local boards of education training in AIDS/HIV prevention, and monitors statewide mandate to provide AIDS education messages to elementary, middle, and senior high schools.

### *Local Health Departments*

- Baltimore City (410) 369-4387
- Upper Eastern Shore (410) 228-3223
- Western Maryland Regional (410) 876-4967
- AIDS Professional Education Center* (410) 328-8639  
The Education Center incorporates the following functions: training community primary providers to incorporate strategies for HIV prevention into their clinical priorities; training selected individuals to serve as HIV educators of health care personnel in their local areas; emphasize HIV training for minority providers; implement needs assessments, placing an emphasis on AIDS epicenters, and establish linkages with existing clinical trials groups.

### **Professional Organizations**

- American Society of Hospital Pharmacists* (301) 657-3000  
Provides consumer drug information, databases, electronic media.
- National Association of Social Workers* (301) 565-0333  
Published policy entitled "AIDS: A Social Work Response"; continuing education and training in AIDS/HIV.
- National Found. for Infectious Diseases* (301) 656-0003  
Education and research to assist in prevention and/or cure of AIDS and all infectious diseases (affiliate of the National Coalition on AIDS).
- National Hemophilia Foundation* (410) 525-3474  
Education, counseling, hotlines, and referral services. ■

**Coming in the March issue...**  
MPhA's Annual  
Third-Party Directory

# Continuing Education

## Continuing Education Quiz

February 1992

Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA Members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by August 31, 1992. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

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Is this program used to meet your mandatory CE requirements? ☐ Yes ☐ No

Was this issue/article useful to your in your practice? ☐ Yes ☐ No

**The questions for this month's continuing education quiz are drawn from the articles on AIDS throughout the February 1992 journal.**

1. AIDS is \_\_\_\_\_ in the world.
  - a. epidemic
  - b. endemic
  - c. pandemic
2. PWA means:
  - a. Pro-Women's Association
  - b. Patients With AIDS
  - c. Pharmacists World Association
  - d. Patients Welfare Association
3. Anti-retrovirals used in treating HIV infection include:
  - a. zidovudine and pentamidine
  - b. Diflucan and ddI
  - c. Roferon and AZT
  - d. zidovudine and didanosine
4. Toxoplasmosis, an opportunistic infection, is treated with:
  - a. pyrimethamine
  - b. Diflucan
  - c. ketoconazole
5. Cachexia may be improved by the use of:
  - a. BW566
  - b. spiramycin
  - c. megestrol acetate
  - d. sandostatin
6. Ketoconazole is used to alleviate:
  - a. candida esophagitis
  - b. gastrointestinal reflux disease
  - c. recurrent chlamydia infections
7. Nutrition plays an important rôle in the treatment of the HIV infected patient. The most devastating threats to proper nutrition are:
  - a. weight loss and insomnia
  - b. diarrhea and frequent urination
  - c. inability to absorb fats and chronic diarrhea
  - d. none of the above
8. AIDS is transmitted by:
  - a. direct physical contact
  - b. airborne viruses
  - c. exchange of body fluids/sexual intercourse
  - d. sharing eating utensils
9. Pentamidine use may cause all of the following adverse reactions except:
  - a. chest pain
  - b. congestion and dyspnea
  - c. dermatitis
  - d. parasthesias
10. Current research shows that Didanosine (ddI) significantly reduces the progression of HIV infection and increases survival rates.
  - a. true
  - b. false

# Classified

"Rx" LICENSE PLATES are still available through MPhA. When you receive your license renewal form, contact Mary Ann at (410) 727-0746 for details. The plates say "Pharmacist Association" in addition to "RX" and the number. This offer is open only to members and their immediate family.

**THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION**, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (410) 358-7036.

**FREE CLASSIFIEDS.** MPha members may place a classified ad at no cost in the journal. Send your written ad to 650 West Lombard Street, Baltimore, MD 21201 or FAX it to (410) 727-2253.

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**OC DELUXE CONDO** Bay front, first floor, overlooking bay and pool, 2 BR, 2 baths, sleeps 6-8. Cable, ice maker, w/d, nicely furnished. 10% discount to pharmacists. Call Albert Katz at (301) 761-3443 or (301) 484-5020.

**THINKING OF RETIRING?** Motivated, energetic pharmacist looking to buy a profitable retail pharmacy. Some owner financing is desired. Please contact through the MPhA office at (800) 833-7587 - BOX B2.

**155 PHARMACISTS AVAILABLE** for retail, hospital, and institutional pharmacy positions. We're ready and able to meet your needs for holiday, vacation, illness or any time you need pharmacy coverage. Need a pharmacist? Call (410) 659-STAT.

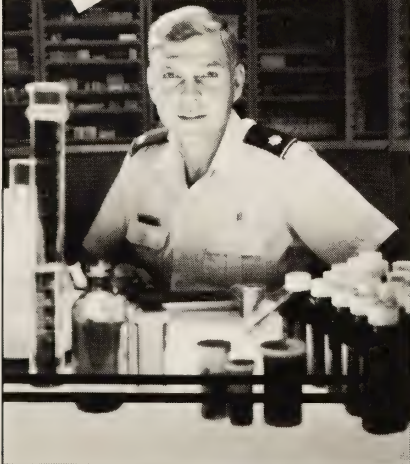
**PHARMACY FOR SALE** Owner wishes to retire. Excellent opportunity for pharmacist to purchase established, profitable practice. Call (800) 833-7587 - BOX P2.

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**PHARMACISTS REHABILITATION COMMITTEE** For private, confidential referrals call (410) 727-0746 or (410) 328-7513.

**THINKING OF SELLING** your successful pharmacy in the Baltimore area? If so, we'd like to chat with you about our acquisition program. Call Jan Patrick in Medicine Shoppe International Acquisition Department, (800) 325-1397.

# AIM HIGH



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# The Maryland Pharmacist

VOL. 68

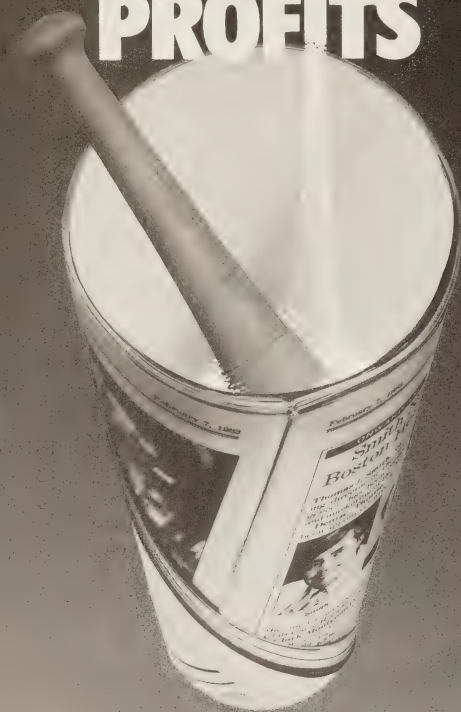
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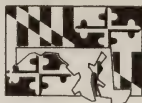
*The 1992 MPhA  
Third-Party Directory*

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# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association  
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March 1992

Volume 68

Number 3

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## President's Commentary

*Ilene H. Zuckerman, Pharm.D., MPhA President*



Third party plans.... According to many pharmacists, this is **the** single most important issue in pharmacy today. With hundreds of combinations of processors, formularies, exclusions, copays, deductibles and other rules to follow, it is nearly impossible for pharmacists to manage the paperwork load associated with filling prescriptions. One MPhA member, Phil Weiner, P.D., has calculated that for every hour his pharmacy is open, he spends two hours of pharmacist and staff time on paperwork. Needless to say, this leaves little time to provide state-of-the-art pharmaceutical care.

Almost daily, I hear "complaints" (although I like to think of these complaints as constructive criticism) about MPhA's lack of involvement in third-party issues. "What is **my** association doing about this mess? I pay dues.... do something!" "How can you allow that contract to pay AWP-10% plus \$1.00 fee?"

Unfortunately, due to federal laws and regulations, there are major constraints on what a group of pharmacists can do about many of the third-party problems. This is somewhat of a confusing issue for pharmacists, since it appears that our professional association could easily rectify some of these issues. Just to give you an example, here is a list of tasks that we can do (and are doing) and tasks that we are prohibited from doing:

### ***WE CANNOT***

Negotiate contracts for members.

Advise you to accept or reject a third-party plan.

Discuss pricing policies for pharmacies.

Boycott a pharmacy plan or a company's product because of dissatisfaction with a particular benefit package.

### ***BUT WE CAN***

Inform you of new contract opportunities.

Give you information of a plan's coverage and limitations.

Pursue legislation to mandate consumer access to the pharmacy of their choice.

Pursue legislation to mandate timely notice of plan changes.

Educate benefit administrators about pharmacy's position.

Provide educational programs about evaluating the economic impact of new contracts.

Seek reimbursement for nondispensing services.

I welcome your continued "constructive criticism." But please keep in mind the "cans" and "cannots" when you ask MPhA for help. Under the leadership of Phil Marsiglia, P.D., MPhA's Third-Party Committee is actively pursuing *all* of the tasks that we *can* do. He and his committee members deserve our accolades for an outstanding performance. ■

## MPhA's 1992 Third-Party Program Directory

David G. Miller, P.D., MPhA Executive Director

When MPhA first published a third-party directory in 1982, the information fit in a two-page chart. Starting in 1990, the directory became an annual issue for *The Maryland Pharmacist*. That year, there were six pages of charts. In 1991, there were also six pages of charts plus additional information.

With changes in third-party programs occurring on a daily basis, MPhA has completely redesigned this year's directory. As you can see from the following pages, we have devoted at least one-half page to each third-party program and provided sufficient room for you to make notes or comments on programs.

We hope that you find this year's directory as useful as our previous issues.

### Guide to the Directory

To help you understand the information for each plan in the directory, you should first read through this section. Although some things are self-explanatory, we were unable to put all information available about a third-party program in its section. If in doubt, contact the third-party directly at the numbers provided.

**Cost Basis** how does the third-party define cost for reimbursement -- AWP is Average Wholesale Price, WAC is Wholesale Acquisition Price, etc. For some programs like PCS, MD-IPA, and Express Scripts, the cost basis varies depending on each pharmacy's contract with that program.

**Method of Billing** shows what billing formats the third-party will accept. More and more third-parties are refusing universal claim forms (UCF) or other paper claims. Expect nearly all third-parties to require on-line electronic claims processing within the next few years.

**Dependent Age** shows the maximum age for which a program subscriber's children has prescription benefit coverage. In many instances you will see "19/23." This means that dependents up to age 19 have coverage; full-time students, up to age 23, also have coverage. Other programs require each covered patient to have their own individual card.

**Doctor List** indicates whether select prescribers prescriptions are considered payable by the plan. Be aware that some plans, especially HMOs, do not cover emergency room prescriptions. Some do not cover dental prescriptions.

**Days Supply** lists the maximum days supply or quantity allowed per prescription by the plan. In some instances, this is the greater of either the days supply or the listed quantity. In other instances it is the lesser of the two.

**Processor** shows what company is providing the claim processing service for the program. The days of submitting claims directly to the HMO or insurer are fading fast. Where possible, we have also included the mnemonic code used by on-line processors.

---

***MPhA is the only state pharmacy association that publishes an annual third-party guide for its members!***

---

**Smoking Cessation products**, including nicotine gum, patches, and OTC products are not covered by most plans. However, some plans do provide limited coverage or coverage subject to prior authorization.

**Contraceptives** covered by plans are usually limited to birth control pills. Some third-parties allow pharmacists to dispense more than one pack per prescription; however, the patient may be required to pay an additional copay.

**Insulin** is covered by most programs. Depending on plan guidelines, more than one vial may be dispensed per prescription. As with contraceptives, the plan may require the patient to pay an additional copay for more than one vial. Where known, we have indicated that in the directory.

**Syringes/Diabetic Supplies** are covered by some plans and are subject to different maximum quantities. Other plans do not cover these products at all.

**Injections** show whether injectable products other than insulin are covered by the program. Since most injectables are prescriber administered, these generally are not covered under the patient's prescription benefit but under their medical benefits. A few exceptions include the Epi-Pen and Anakit for allergic reactions.

The MPhA Third-Party Directory constitutes four months of effort by the MPhA staff and committee members. A special note of thanks is due to Melvin Rubin, P.D. who is responsible for helping start this directory and working with MPhA to provide the most accurate and timely information possible to you, our members.

## Aetna

Aetna Pharmacy Management  
MC17

151 Farmington Avenue  
Hartford, Connecticut 06156

(203) 636-8313

(800) 333-9851

(800) 441-3098 *Help Desk, Eligibility verification*

Cost Basis:	AWP
Dispensing Fee:	Lesser of U/C or discounted fee.
Method of Billing:	On-line
Dependent Age:	19/23
Refills Allowed:	1 year
Generics Required:	Yes, for most plans
Doctor List:	Yes, for most plans
Pre-Authorization:	For "DAW" prescriptions
Maximum Days/Dosage:	Most plans have a 30 day supply limit. Some plans allow 100 days supply.
Maintenance List:	Some groups, check plan guidelines
Maryland Rx's Only:	If "2" appears on patient's card
Processor:	Aetna

### Special Items

Smoking Cessation:	Covered for some groups
Rogaine:	No
Retin A:	Yes, for some groups only
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes, for some groups only
Rx Vitamins:	Yes
Anorectics:	No
Contraceptives:	Yes, for some groups only
Diaphragms/Devices:	No
Insulin:	Yes, up to a 30 day supply
Syringes:	Insulin syringes only
Diabetic Supplies:	Yes, for some groups only
Injections:	No

## Alta Administrators

Alta Administrators  
(formerly USA Administrators)  
3540 Wilshire Boulevard  
Los Angeles, California 90010  
(213) 383-1100

Cost Basis:	WAC + 2.6%
Dispensing Fee:	\$5.00
Method of Billing:	UCF/tape/electronic
Dependent Age:	List sent to pharmacy
Refills Allowed:	By law
Generics Required:	State formulary
Doctor List:	No
Pre-Authorization Required:	No
Maximum Days/Dosage:	34 day supply, some have a 90 day supply list
Maintenance List:	Yes, by therapeutic class
Maryland Rx's Only:	Yes
Processor:	Alta Administrators

### Special Items

Smoking Cessation:	No
Rogaine:	No
Retin A:	Yes
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes
Rx Vitamins:	Yes
Anorectics:	Yes
Contraceptives:	Some plans allow up to 3 packs.
Diaphragms/Devices:	No
Insulin :	Yes, up to a 90 day supply
Syringes:	Insulin syringes only
Diabetic Supplies:	Supplies only, no devices are covered.
Injections:	No

*Notes:* No dental prescriptions are covered.

# APS

Associated Prescription Services  
2811 Baltimore Drive  
Baltimore, Maryland 21207  
(410) 944-2700 -- Baltimore  
(410) 621-5150 -- Washington, DC  
(800) 962-3784

Cost Basis: AWP or AWP-10%  
Dispensing Fee: Varies  
Method of Billing: UCF/tape/electronic  
Dependent Age: Most are 19/23  
Refills Allowed: By law  
Generics Required: See card. If generic, use the Maryland State Formulary.  
  
Doctor List: No  
Pre-Authorization: If greater than \$200  
Days Supply: See chart below.  
Maintenance List: Yes, see manual  
Maryland Rx's Only: Yes  
Processor: APS

## Special Items

Smoking Cessation: POS verification  
Rogaine: POS verification  
Retin A: POS verification  
Cyclosporine: POS verification  
Retrovir: POS verification  
Fertility: POS verification  
Rx Vitamins: POS verification  
Anorectics: POS verification  
Contraceptives: Up to 3 packs per prescription  
Diaphragms/Devices: POS verification  
Insulin: Yes  
Syringes: Plan 9, code "S" or "F" only  
Diabetic Supplies: No, unless code "F" on card.  
Injections: Some plans.

*Notes:* \$1.25 compound fee. APS point-of-sale (POS) verification system ascertains whether the patient has coverage for special prescription items. A manual sent to pharmacies by APS lists groups which include or exclude these items but is not as up-to-date as the POS.

All plans cover legend drugs unless specifically excluded by the plan. All plans exclude immunological agents and appliances unless otherwise excluded. All plans include compounded prescriptions if at least one ingredient is a federal Legend Drug in a therapeutic amount. Any drug or prescription prescribed for other than the Federally approved usage will not be paid for unless authorized by the Fund. Some plans allow "DAW-1" overrides.

For all accounts, the ingredient cost should not exceed \$100 without prior authorization.

## Plan Code Limitations and Exceptions

**A** Up to a 100 day supply.  
**B** Up to a 34 day supply or 100 doses, whichever is greater.  
**C** Up to a 34 day supply only.  
**D** Up to a 34 day supply or 100 day supply for Approved Maintenance Drugs  
**E** Up to a 34 day supply or 100 doses whichever is greater.  
**F** Insulin syringes and needles, and testing products that are used to detect or monitor diabetes (Clinistix, Chemstrip, etc.) on prescription only.  
**G** Generic plan (See #9 in policies and procedures)  
**K** Diaphragms covered for member or spouse only.  
**N** No vitamins, whether legend or not.  
**P** No fertility drugs  
**S** Insulin syringes and needles covered on prescription only.  
**W** No diet pills.  
**Z** No smoking deterrents (*ie:* Nicorette, Nicoderm).

Plan Number	Oral Contr.	OTC Products	Injectables	Insulin	Miscellaneous
1	Yes	Yes	Yes	Yes	
2	No	No	No	Yes	
3	Yes	Yes	No	Yes	
4	No	Yes	No	Yes	
5	Yes	No	No	Yes	
6	No	No	Yes	Yes	
7	Yes	No	Yes	Yes	
8	No	Yes	Yes	Yes	
9	No	No	No	Yes	No Vitamins

# Blue Cross of Maryland

## Blue Cross of Maryland

10455 Mill Run Circle  
Owings Mills, Maryland 21117  
(410) 581-3000 *General Information*  
(410) 581-3535 or (800) 248-3410 *Blue Line*  
(410) 581-3542 or (800) 782-9986 *Pharmacy Claims*  
(800) 421-2342 *Provider Relations*  
(800) 421-2342 *BC/BS Eligibility*  
(410) 998-5480 *Fraud and Abuse*  
(410) 560-3790 *Pharmacy Relations/Paradigm*  
(800) 492-4209 *GM Plan Information*

Most Blue Cross claims go to:

PHS  
Post Office Box 80716  
Los Angeles, California 90080  
(800) 421-2342 *Help Desk*  
(800) 835-3330 *Eligibility Verification*  
(800) 421-2343 *PHS Information, Extension 3*

Cost Basis:	Acquisition
Dispensing Fee:	\$ 3.30
Method of Billing:	UCF/tape/on-line
Dependent Age:	19/23
Refills Allowed:	1 year
Generics Required:	Yes, *PPD with a few exceptions
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Lesser of 34 days supply or 100 doses
Maintenance List:	Yes
Maryland Rx's Only:	Yes
Processor:	PHS for Blue Cross
Mnemonic:	BCBSM

### Special Items

Smoking Cessation:	Yes
Rogaine:	No
Retin A:	Yes, for acne only
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes
Rx Vitamins:	Yes
Anorectics:	No
Contraceptives:	If "PCD" on card, 3 months
Diaphragms/Devices:	No
Insulin:	Yes, up to 4 vials/copy
Syringes:	No
Diabetic Supplies:	No
Injections:	Yes

# Blue Cross of Maryland

## Baltimore City Employees

Claims go to PHS

Cost Basis:	Acquisition
Dispensing Fee:	\$ 3.30
Method of Billing:	UCF/tape/on-line
Dependent Age:	19/23
Refills Allowed:	1 year
Generics Required:	Yes, *PPD with a few exceptions
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Lesser of 34 days supply or 100 doses
Maintenance List:	Yes, up to 100 days supply
Maryland Rx's Only:	Yes
Processor:	PHS for Blue Cross

### Special Items

Smoking Cessation:	Yes
Rogaine:	No
Retin A:	Yes, for acne only
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes
Rx Vitamins:	No
Anorectics:	No
Contraceptives:	If "PCD" on card, 3 months
Diaphragms/Devices:	No
Insulin:	Yes, up to 4 vials/copy
Syringes:	No
Diabetic Supplies:	No
Injections:	Yes

**Notes:** \*PPD - patient pays difference when a brand name product is available or required. General Motors employees have a \$5.00 copay *except* if they are members of a PPO and then the copay is \$3.00. All claims should reflect a complete and correct birthdate for the patient. All Blue Cross programs require 1 copay for 34 days supply for items not on maintenance lists. If on maintenance lists, 1 copay per maximum day supply is allowed. **Claims for General Motors, K-Mart, UAW cannot be submitted to PHS.** Send UCF claims to: BCBS of MD, PO Box 1694, Cumberland, MD 21501-1694. Other national accounts go to PHS as above. Worcester County employees still go through PCS. BCBS IMD Program has a \$50 annual deductible and a \$750 quarterly maximum benefit. Copays are 20% of ingredient costs for generics and 30% of cost for brands.

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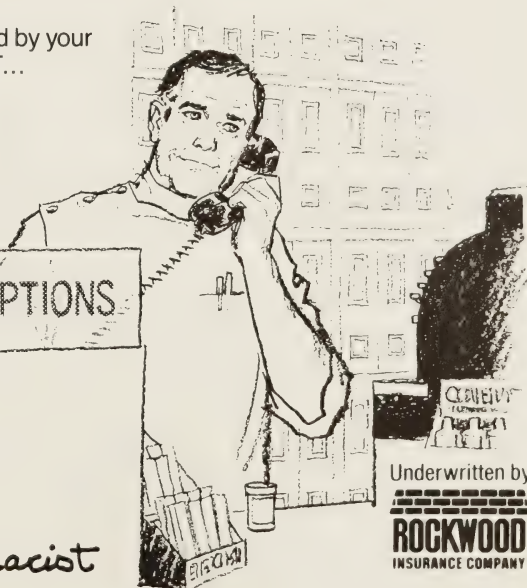
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104 CHURCH LANE / BALTIMORE, MARYLAND 21208 / (301) 484-7000

# Care First

*Also trades as Potomac Health.*

PHS  
PO Box 80716  
Los Angeles, California 90080  
(310) 391-1133  
(800) 421-2342  
(410) 355-3600 *Local*  
(410) 560-3790 *Paradigm Management*

Cost Basis:	AWP-10%
Dispensing Fee:	\$3.00
Method of Billing:	UCF/tape/On-line
Dependent Age:	By card
Refills Allowed:	By Law
Generics Required:	PHS Formulary, *PPD
Doctor List:	No
Pre-Authorization:	No
Days Supply:	34 days supply
Maintenance List:	No
Maryland Rx's Only:	Yes
Processor:	PHS for Care First Managed by Paradigm.
Mnemonic:	HCCMA for Care First HCCP for Potomac Health

## Special Items

Smoking Cessation:	Yes
Rogaine:	Pre-authorization required
Retin A:	Yes, up to age 26
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes
Rx Vitamins:	Yes
Anorectics:	No
Contraceptives:	Yes, if RX/C on card
Diaphragms/Devices:	Yes, if RX/C on card
Insulin:	Yes
Syringes:	No
Diabetic Supplies:	No
Injections:	Yes

*Notes:* \*PPD - patient pays difference if patient or prescriber requests brand when generic alternative is available. No anabolic hormones are covered. Some brands are not reimburseable (e.g., Triphasil, Norinyl, Ortho-Novum, insulins). See formulary for alternatives.

# Carpenters Benefit Fund

432 Eastern Boulevard  
Baltimore, Maryland 21221  
(410) 686-2700  
(800) 899-4464

Cost Basis:	AWP
Dispensing Fee:	\$2.60
Method of Billing:	UCF/tape
Dependent Age:	19/23
Refills Allowed:	By Law
Generics Required:	Yes, *PPD
Doctor List:	No
Pre-Authorization:	If Rx costs more than \$200
Days Supply:	Greater of 34 days supply or 100 doses
Maintenance List:	90 days supply
Maryland Rx's Only:	Yes
Processor:	Carpenters Benefit Fund

## Special Items

Smoking Cessation:	Yes
Rogaine:	No
Retin A:	Yes, for acne only
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Pre-authorization only
Rx Vitamins:	Yes
Anorectics:	Yes
Contraceptives:	Yes
Diaphragms/Devices:	No
Insulin:	Yes
Syringes:	Yes
Diabetic Supplies:	No
Injections:	No

*Notes:* \*PPD - patient pays difference if patient or prescriber requests brand when generic alternative is available.

# Chesapeake Health Plan

PHS  
PO Box 80716  
Los Angeles, California 90080  
(310) 391-1133  
(800) 421-2342  
(410) 285-8000 *Local General*  
(410) 539-8622 *Local Pre-authorization*

Cost Basis:	AWP-10%
Dispensing Fee:	\$3.00
Method of Billing:	Tape/On-line
Dependent Age:	By card
Refills Allowed:	2
Generics Required:	PHS Formulary, *PPD
Doctor List:	No
Pre-Authorization:	For prescriptions costing more than \$100 except for chronic drugs.
Days Supply:	Greater of 34 days supply or 100 doses. Pre-authorization is required for greater than this except for chronic drugs.
Maintenance List:	Yes
Maryland Rx's Only:	Yes
Processor:	PHS for Chesapeake Health Plan
Mnemonic:	CHES

## Special Items

Smoking Cessation:	Yes
Rogaine:	No
Retin A:	Yes, up to age 25
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes, if "BC" on card.
Rx Vitamins:	Yes
Anorectics:	No
Contraceptives:	Yes, if "BC" on card, 3 packs
Diaphragms/Devices:	Yes, if "R-BC" on card
Insulin:	Yes, up to 4 vials
Syringes:	Yes, 100 maximum per prescription
Diabetic Supplies:	Group 5500 only: test strips, sticks, devices, lancets Group 5078 only: test strips, sticks, tablets
Injections:	No

*Notes:* \*PPD - patient pays difference if patient or prescriber requests brand when generic alternative is available. Group 5500 series plans cover same items as Medicaid. Chesapeake Health Plan excludes some name brands in favor of identical brands (eg. Calan SR instead of Isoptin SR). Refer to list provided by the program or the on-line information. The Chesapeake Formulary may differ from the standard Columbia/Freestate Formulary. Chesapeake Health Plan covers some medical supplies, no progesterone suppositories. Cards marked "BC" cover birth control pills only. Cards marked "R-BC" cover birth control pills and prescriptions. There are no copayments for nursing home patients. Temporary cards cover oral contraceptives, diaphragms, fertility products, and diabetic tests. Some plans have a \$1,000 annual maximum. Chesapeake requires generic alternatives for certain birth control cycles and for Entex LA.

Pre-authorized medical supplies must be billed directly to the appropriate Chesapeake site.

## Switch Agent Directory

NDC ..... (800) 622-2316  
*National Data Corporation*

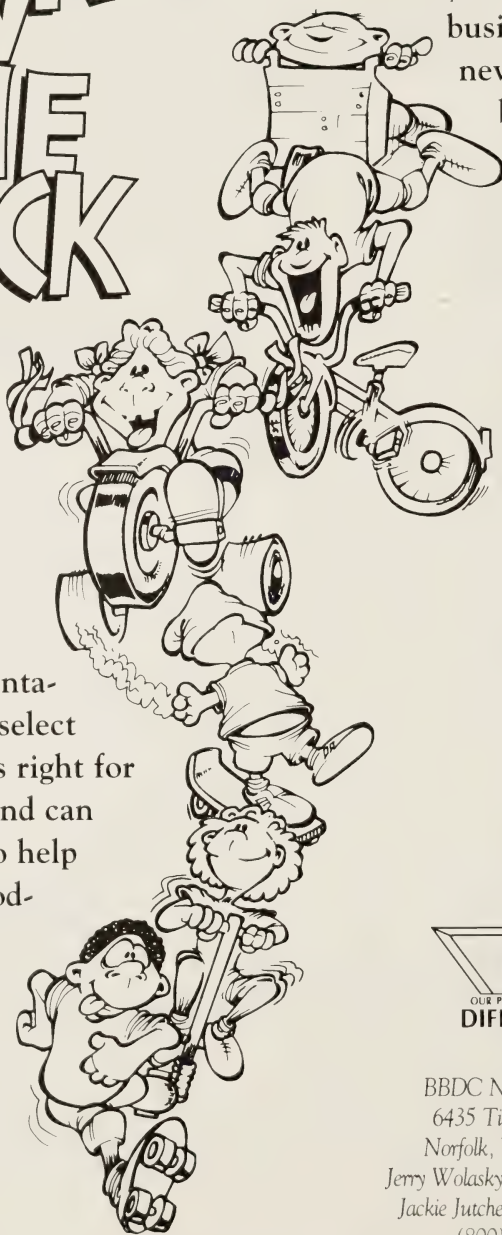
Envoy ..... (800) 333-6869

GCC ..... (800) 433-4893  
*General Computer Company*

# WE'RE NOT THE NEW KIDS ON THE BLOCK

We're Bergen Brunswig Drug Company. We've been serving pharmacies just like yours for over 100 years. Our professional sales representatives can help you select merchandise that is right for your trading area and can provide the tools to help you price those products competitively. Our merchandisers make sure that your products are effectively displayed for maximum sell through. Our drivers are

prompt and courteous. And, our customer service representatives are ready to answer your questions and inquiries. Bergen Brunswig Drug Company — we're your partners in business, not the new kids on the block.



BBDC Norfolk Division  
6435 Tidewater Drive  
Norfolk, Virginia 23509  
Jerry Wolasky, Division Manager  
Jackie Jutchess, Sales Manager  
(800) 446-8209

## CIGNA Mid-Atlantic

Argus Health Systems  
1055 Broadway  
Kansas City, Missouri 64105  
(800) 522-7487

Cost Basis:	AWP or contracted amount
Dispensing Fee:	Varies
Method of Billing:	UCF/on-line
Dependent Age:	By card
Refills Allowed:	1 year
Generics Required:	Yes
Doctor List:	No, DEA number required
Pre-Authorization:	No
Days Supply:	Lesser of 34 days supply or 100 doses.
Maintenance List:	For some plans
Maryland Rx's Only:	Yes
Processor:	Argus for CIGNA Mid-Atlantic

### Special Items

Smoking Cessation:	No
Rogaine:	No
Retin A:	Most, up to age 25 or preautho
Cyclosporine:	No
Retrovir:	Preauthorization required
Fertility:	Yes, for most plans
Rx Vitamins:	Only for some plans
Anorectics:	No, for most plans
Contraceptives:	Yes, but for only a few plans
Diaphragms/Devices:	No
Insulin:	Yes
Syringes:	No, for most plans
Diabetic Supplies:	No, for most plans
Injections:	No

*Notes:* Compound NDC for CIGNA Mid-Atlantic 77777-7777-77.

## Diversified Pharmaceutical Services

Diversified Pharmaceutical Services  
PO Box 1459, Route 9720  
Minneapolis, Minnesota 55440-1459  
(612) 830-3166  
(800) 233-8065

Cost Basis:	AWP-10%
Dispensing Fee:	\$2.00
Method of Billing:	On-line
Dependent Age:	By card
Refills Allowed:	1 year
Generics Required:	Yes, *PPD
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Most plans have a maximum 34 days supply limit. Some plans allow 34 days or 100 doses.
Maintenance List:	100 doses allowed for some plans
Maryland Rx's Only:	Yes
Processor:	DPS
Mnemonic:	Varies with plan. Also has suffix code.

### Special Items

Smoking Cessation:	Some plans
Rogaine:	Most plans, no
Retin A:	Some plans
Cyclosporine:	Yes
Retrovir:	Some plans
Fertility:	Some plans
Rx Vitamins:	Yes
Anorectics:	No
Contraceptives:	Some plans
Diaphragms/Devices:	Some plans
Insulin:	Yes, 34 day supply
Syringes:	Some plans, for insulin only
Diabetic Supplies:	Yes, for most plans
Injections:	Yes

*Notes:* \*PPD - patient pays difference if patient or prescriber requests brand when generic alternative is available. Yocon and growth hormones are not covered. Manual claims should be sent to DPS, Route 4880, PO Box 59005, Minneapolis, MN 55440-0005.

## Express Scripts (PERx)

Express Scripts  
2369 Schuetz Road  
St. Louis, Missouri 63146  
(800) 553-3750

Cost Basis:	Varies by plan
Dispensing Fee:	Varies by plan
Method of Billing:	UCF/tape
Dependent Age:	Varies
Refills Allowed:	By law.
Generics Required:	Recommended
Doctor List:	No
Pre-Authorization:	Varies by plan
Days Supply:	Varies by plan
Maintenance List:	Yes
Maryland Rx's Only:	Yes
Processor:	PERx, a.k.a. Express Scripts

### Special Items

Smoking Cessation:	Varies by plan
Rogaine:	Varies by plan
Retin A:	Varies by plan
Cyclosporine:	Varies by plan
Retrovir:	Varies by plan
Fertility:	Varies by plan
Rx Vitamins:	Varies by plan
Anorectics:	Varies by plan
Contraceptives:	Some plans allow 1 month supply
Diaphragms/Devices:	Varies by plan
Insulin:	Yes, up to 3 vials
Syringes:	Varies by plan
Diabetic Supplies:	Varies by plan
Injections:	Varies by plan

Notes: \*PPD - patient pays difference for branded prescriptions when generic is available.

## Free State HMO

PHS  
PO Box 80716  
Los Angeles, California 90080  
(310) 391-1133  
(800) 421-2342  
(410) 560-3790 *Local General*  
(410) 560-3792 *Local Pre-authorization*

Cost Basis:	AWP-10%
Dispensing Fee:	\$ 3.00
Method of Billing:	UCF/tape/on-line
Dependent Age:	By card.
Refills Allowed:	By law.
Generics Required:	Formulary, *PPD
Doctor List:	Yes
Pre-Authorization:	Some drugs, see Formulary.
Days Supply:	Greater of 34 days supply or 100 doses
Maintenance List:	See Formulary
Maryland Rx's Only:	Yes
Processor:	PHS for Free State HMO Managed by Paradigm
Mnemonic:	Free

### Special Items

Smoking Cessation:	No
Rogaine:	No
Retin A:	Yes
Cyclosporine:	Yes
Retrovir:	Pre-authorization
Fertility:	No
Rx Vitamins:	No
Anorectics:	Amphetamines only
Contraceptives:	Most plans cover, 3 packs for 1 copay
Diaphragms/Devices:	Yes, some plans only
Insulin:	Yes
Syringes:	Yes
Diabetic Supplies:	No, unless on card
Injections:	No

Notes: Free State requires generics on all prescriptions except analeptics and some cardiovasculars. Refer to the Free State Formulary covered drugs and generic policies. Certain brand name drugs require alternates (some oral contraceptives, insulins, etc.). For a vacation supply, use a UCF and mark it "VACATION." Accutane and Cytotec are not covered for women over 30.

## Health Care 2000

c/o D & P Processing  
1063 Maiden Choice Lane  
Catonsville, Maryland 21229  
(410) 247-1244 -- Baltimore  
(410) 296-8326 -- Preauthorization, membership

Cost Basis:	AWP
Dispensing Fee:	+ 8%
Method of Billing:	UCF
Dependent Age:	19/23
Refills Allowed:	6
Generics Required:	Medicaid IDC list, *PPD
Doctor List:	Yes
Pre-Authorization:	For Ornade, Seldane, Hismanal, Accutane, dental prescriptions
Days Supply:	34 day supply
Maintenance List:	No
Maryland Rx's Only:	Yes
Processor:	D&P for Health Care 2000

### Special Items

Smoking Cessation:	No
Rogaine:	No
Retin A:	For acne only, Pre-authorization
Cyclosporine:	Pre-authorization
Retrovir:	Pre-authorization
Fertility:	Pre-authorization
Rx Vitamins:	No
Anorectics:	No
Contraceptives:	3 packs for 3 copays No coverage for Groups 250-254
Diaphragms/Devices:	No
Insulin:	Yes, up to 4 vials
Syringes:	100 per prescription
Diabetic Supplies:	No
Injections:	No

*Notes:* No dietary supplements are covered. Use Medicaid pharmacy provider ID as pharmacy ID number on claims. No emergency room prescriptions are covered, patient must pay for prescription and seek own reimbursement except Bethlehem Steel employees.

## Health Net Sinai Care

*Most patients are covered through APS; only Maryland National Bank employees go through D&P Processing.*

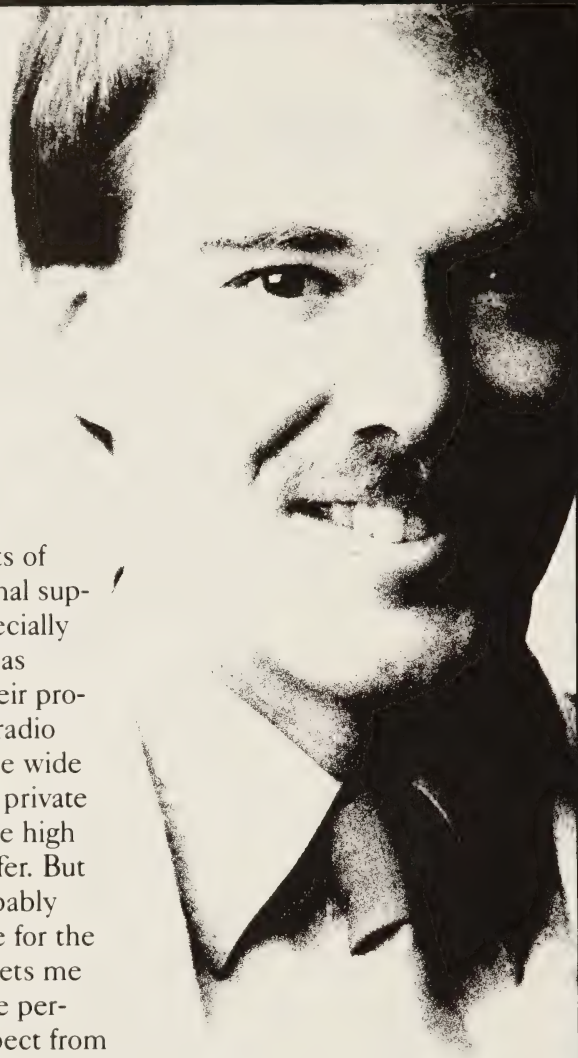
c/o D & P Processing  
1063 Maiden Choice Lane  
Catonsville, Maryland 21229  
(410) 247-1244 -- Claims  
(410) 578-5130 -- Preauthorization, membership

Cost Basis:	AWP
Dispensing Fee:	\$2.50
Method of Billing:	UCF
Dependent Age:	19/23
Refills Allowed:	By Law
Generics Required:	Medicaid List, *PPD
Doctor List:	Yes
Pre-Authorization:	Yes, for a few drugs
Days Supply:	34 days supply or 100 doses
Maintenance List:	No
Maryland Rx's Only:	Yes
Processor:	APS or D&P Processing

### Special Items

Smoking Cessation:	Pre-authorization
Rogaine:	Yes
Retin A:	Yes
Cyclosporine:	Yes
Retrovir:	Pre-authorization
Fertility:	Yes
Rx Vitamins:	Yes
Anorectics:	Yes
Contraceptives:	Yes
Diaphragms/Devices:	No
Insulin:	Yes
Syringes:	Yes
Diabetic Supplies:	No
Injections:	Yes, if self-administered

*Notes:* \*PPD - patient pays difference if patient or prescriber requests brand when generic alternative is available. Use Medicaid pharmacy provider ID as pharmacy ID number on claims. No emergency room prescriptions are covered, patient must pay for prescription and seek own reimbursement.



**“Over 3,000  
pharmacies  
belong to  
Valu-Rite.  
There must  
be a reason.**

**I**n fact, there are lots of reasons. Promotional support for example, especially now that McKesson has added cable TV to their program of circulars and radio spots. Then there's the wide selection of Valu-Rite private label products, and the high profit margins they offer. But most pharmacies probably sign on with Valu-Rite for the same reason I did: it lets me give my customers the personal service they expect from an independent, along with the low prices of a national chain. That's a combination that just can't be beat.”

*Scott Rickards*

**SCOTT RICKARDS**  
RICKSAVE DRUG  
NAPLES, MAINE

**McKesson**

# Iron Workers Local #16

6229 North Charles Street  
Baltimore, Maryland 21212

Cost Basis:	AWP
Dispensing Fee:	\$2.50
Method of Billing:	UCF
Dependent Age:	19/23
Refills Allowed:	5
Generics Required:	No
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Greater of 34 days or 100 doses
Maintenance List:	No
Maryland Rx's Only:	Yes
Processor:	Iron Workers Local #16

## Special Items

Smoking Cessation:	No
Rogaine:	No
Retin A:	Yes, up to age 19
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes
Rx Vitamins:	No
Anorectics:	No
Contraceptives:	No
Diaphragms/Devices:	No
Insulin:	No
Syringes:	No
Diabetic Supplies:	No
Injections:	No

# Kaiser Permanente

Kaiser Permanente Drug/Optical Benefits  
Post Office Box 9800  
Washington, DC 20016  
(800) 368-5787 *Pre-authorization, membership*  
(202) 364-3485 or 364-4868 *Billing*  
(202) 364-3400 *Pre-authorization, membership*  
(202) 364-3428 *NABP Registration*  
(800) 622-2316 *Line Problems*  
(410) 281-6116 *Woodlawn Pharmacy*  
(202) 364-6733 *Override Authorization*

Cost Basis:	AWP
Dispensing Fee:	\$3.00
Method of Billing:	UCF/On-line
Dependent Age:	By card
Refills Allowed:	By law
Generics Required:	Medicaid List, *PPD
Doctor List:	Yes
Pre-Authorization:	Yes, for a few drugs
Days Supply:	60 days supply
Maintenance List:	No
Maryland Rx's Only:	Yes
Processor:	Kaiser Permanente

## Special Items

Smoking Cessation:	Yes
Rogaine:	No
Retin A:	Yes, for acne only
Cyclosporine:	Pre-authorization
Retrovir:	Pre-authorization
Fertility:	Pre-authorization
Rx Vitamins:	Yes
Anorectics:	Yes
Contraceptives:	Yes, 2 packs per prescription
Diaphragms/Devices:	No
Insulin:	Yes
Syringes:	Yes
Diabetic Supplies:	Yes, except lancets
Injections:	Yes, if self-administered

*Notes:* \*PPD - patient pays difference if patient or prescriber requests brand when generic alternative is available. Kaiser no longer has reduced copays for Baltimore sites. Some have 50% copays and some have \$50 deductibles. No emergency room prescriptions are permitted. Patient must pay and seek reimbursement from Kaiser directly.

# MD-IPA

MD-IPA  
4 Taft Court  
Rockville, Maryland 20850  
(800) 638-8898  
(301) 294-5029 -- Enrollment

Cost Basis:	AWP less contracted %
Dispensing Fee:	Varies
Method of Billing:	UCF/tape/on-line
Dependent Age:	By card
Refills Allowed:	By law
Generics Required:	Strongly advised
Doctor List:	Yes
Pre-Authorization:	No
Days Supply:	34 days supply or 100 doses
Maintenance List:	Yes
Maryland Rx's Only:	Yes
Processor:	MD-IPA

## Special Items

Smoking Cessation:	No
Rogaine:	No
Retin A:	No
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Yes, Clomid only
Rx Vitamins:	Yes
Anorectics:	Yes
Contraceptives:	Yes, 3 months/copay
Diaphragms/Devices:	No
Insulin:	Yes
Syringes:	Yes, for insulin only
Diabetic Supplies:	No
Injections:	Pre-authorization

*Notes:* Some plans have \$50 deductibles. Cards for plans called "Optimum Choice," "Alliance," or "MAPSI" are all MD-IPA plans.

# Maryland Medical Assistance

Maryland Medicaid Administration  
Department of Health and Mental Hygiene  
201 West Preston Street  
Baltimore, Maryland 21201

## Telephone Directory

Abuse . . . . .	(410) 225-1678 or (410) 333-3020
Drug Coverage Questions (Jim Hodges)	(410) 225-5701
Eligibility Verification . .	(800) 492-2134 <i>Maryland only</i>
Eligibility Verification	(410) 333-3020 <i>Metro Baltimore</i>
Eligibility Verification	(800) 683-5775 <i>Outside Maryland</i>
Fraud . . . . .	(410) 225-1686
HMO Operations . . . . .	(410) 225-1590
Invoice Processing (Operations)	(410) 225-5349
Nutritional Formulations . . . . .	(410) 225-1743
Operations Division .	(410) 225-5349 or (410) 225-5795
Pharmacy Assistance Program . . . . .	(410) 225-5392
Pharmacy Policy Staff Specialist . . . . .	(410) 225-1459
Policy Division . . . . .	(410) 225-1455
Preauthorization . . .	(410) 225-1755 or (800) 492-6008
Provider Enrollment . . . . .	(410) 225-5339
Provider Relations . .	(410) 333-5414 or (800) 445-1159
Refill Invoices . . . . .	contact local health department
Refill Invoices Out-of-State Providers .	(410) 225-5337
Kidney Disease Program . . . . .	(410) 225-5000
Retrovir Authorization . . . . .	(410) 225-6800
Claim Payment Status . . . . .	(410) 333-5414
Diabetes Program . . . . .	(410) 225-5150
Recipient Fraud . . . . .	(410) 225-1686
Verbal Eligibility Authorization . . . . .	(410) 333-5399
Verbal Drug Coverage Authorization . .	(410) 225-1755

## General Notes

*Amphetamines:* Prescriptions for central nervous system stimulants and anorectic agents used for weight control are not covered by Medical Assistance. The use to treat narcolepsy or hypokinesia must be indicated on prescriptions for amphetamines by the physicians in *their own handwriting*. Methylphenidate (Ritalin) prescriptions used for the treatment of ADD in children do not need the diagnosis.

*General Notes:* Generic substitution requirements may be overridden by a prescriber if he/she specifies "brand medically necessary" or "brand necessary" and a diagnosis or explanation in his/her own handwriting on each

prescription. Analeptics marked "BMN" do not have to have a diagnosis noted by the prescriber. The pharmacist must place an "X" in the block in the lower left corner of the claim.

All "brand medically necessary" prescriptions must be submitted on hard-copy. No tape billing is allowed!

You must bill the State the same price you charge a cash customer before any special discounts. You will be paid the lesser of that amount or the cost as defined by the State plus a professional fee.

*Pre-authorization:* If the usual and customary charge for a prescription is more than \$100 and is written for a 34 or more days supply or the cost is greater than \$400, regardless of the days supply, preauthorization should be obtained by calling (410) 225-1755 or (800) 492-6008 beyond the local calling area.

*New Born Policy:* For newborns, use the mother's recipient number and verify the mother's eligibility through EVS before service. Hold the claim for submission until the newborn is entered into the EVS system (about four weeks).

*H<sub>2</sub> Blockers Policy:* First prescriptions must be marked in prescriber's handwriting "initial therapy." Up to a 34 day supply and one refill is allowed.

After that period, prescriptions must be less than the dosage cited below unless the prescriber writes in his or her own handwriting the specific medical conditions.

Zantac (300mg/day)	Tagamet (800mg/day)
Pepcid (40mg/day)	Axid (300mg/day)

*Reimbursable OTC Products:* The following over-the-counter products are covered by Maryland Medical Assistance: insulin, hypodermic needles and syringes, enteric coated aspirin, sole ingredient oral ferrous sulfate products, chewable iron and vitamin tablets for children, family planning drugs and devices.

*Rules for Condoms:* Condoms may be dispensed to Medicaid recipients directly by the pharmacist. Either male or female recipients must personally present an eligible card. Twelve condoms are permitted per prescription. Only lubricated or non-lubricated latex condoms are covered -- no lambskin condoms are permitted.

The pharmacist should use a refill form (DHMH 236) to write up the condom package as a prescription and the patient should sign the form where a prescriber's signature would normally go. Write the word "original" immediately below the refill block on the form. Treat each invoice as a new prescription. The patient is not required to pay any copay.

## Specially Assigned NDC Numbers

Use the following Medical Assistance Assigned Medicaid numbers when submitting claims:

### *Prescription Items*

Compounds . . . . .	00998-0000-00
Disposable U-100 1ml syringes . . . . .	00996-2222-00
Disposable U-100 0.5ml syringes . . . . .	00996-3333-00
All other hypodermics/syringes . . . . .	00996-1111-00
Legend drugs without NDC codes . . . . .	00999-0000-00
Enteral nutrition products . . . . .	00999-1111-00
Non-lubricated condoms . . . . .	00997-1111-00
Lubricated condoms . . . . .	00997-2222-00

If more than one order is dispensed at one time (eg. two compounded prescriptions, use the 00 for the final digits of the code for the first prescription, 01 for the second, etc. This will prevent rejections as duplicate invoices.

### *Home IV Therapies*

Total parenteral nutrition . . . . .	00998-1111-00
Antibiotic therapy . . . . .	00998-2222-00
Chemotherapy . . . . .	00998-3333-00
Pain management therapy . . . . .	00998-4444-00
Fluid replacement therapy . . . . .	00998-5555-00
Hemophilia therapy . . . . .	00998-6666-00
Miscellaneous parenteral therapy . . . . .	00998-7777-00

When dispensing prescriptions for chewable iron with multivitamin tablets and ferrous sulfate prescriptions, use the following NDC codes if the product does not have its own NDC code.

### *Ferrous Sulfate Products*

Chewable iron with vitamin tablets . . . . .	00997-4001-00
Ferrous sulfate drops . . . . .	00997-4002-00
Ferrous sulfate elixir . . . . .	00997-4003-00
Ferrous sulfate syrup . . . . .	00997-4004-00
Ferrous sulfate tablets . . . . .	00997-4005-00
Ferrous sulfate unit dose tablets . . . . .	00997-4006-00

Cost Basis:	EAC (WAC+10%) or IDC List
Dispensing Fee:	Lower of U/C or \$5.91 if cost is <\$36.34 \$7.17 if cost is >\$36.34
Method of Billing:	UCF/tape
Dependent Age:	By individual card.
Refills Allowed:	2
Generics Required:	Yes, see IDC List.
Doctor List:	No
Pre-Authorization:	>\$400 or >\$100 for 34 or greater days supply
Days Supply:	34 days supply, some 100 day supplied allowed 100 doses
Maintenance List:	No
Maryland Rx's Only:	No

#### Special Items

Smoking Cessation:	Yes
Rogaine:	No
Retin A:	Yes
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Through July 1, 1992
Rx Vitamins:	Yes
Anorectics:	No
Contraceptives:	Yes, up to a 6 month supply
Diaphragms/Devices:	Yes
Insulin:	Yes, up to a 100 day supply
Syringes:	Yes
Diabetic Supplies:	Covered under DMS/DME Program
Injections:	Limited to nursing home or home administration.

*Notes:* No DESI drug products are covered. Products from manufacturers who have not signed rebate agreements are not covered. A copayment of 50 cents is required for each prescription or refill from recipients in federal categories except for prescriptions for: individuals under 21 years old, pregnant women, institutionalized individuals, HMO enrollees, family planning drugs and devices. Services to recipients in federal categories cannot be denied because of inability to pay the copayment. Individuals who can afford the copayment are not exempted from paying the copy.

A copy of \$1.25 is required from recipients in State only categories except for prescriptions for: drugs and devices which are Early and Periodic Screening Diagnosis and Treatment (EPSDT) services for individuals; or family planning drugs and devices.

## Metropolitan

Medimet Claims Office  
Oneida County Industrial Park  
Post Office Box 3018  
Utica, New York 13504  
(315) 768-2409

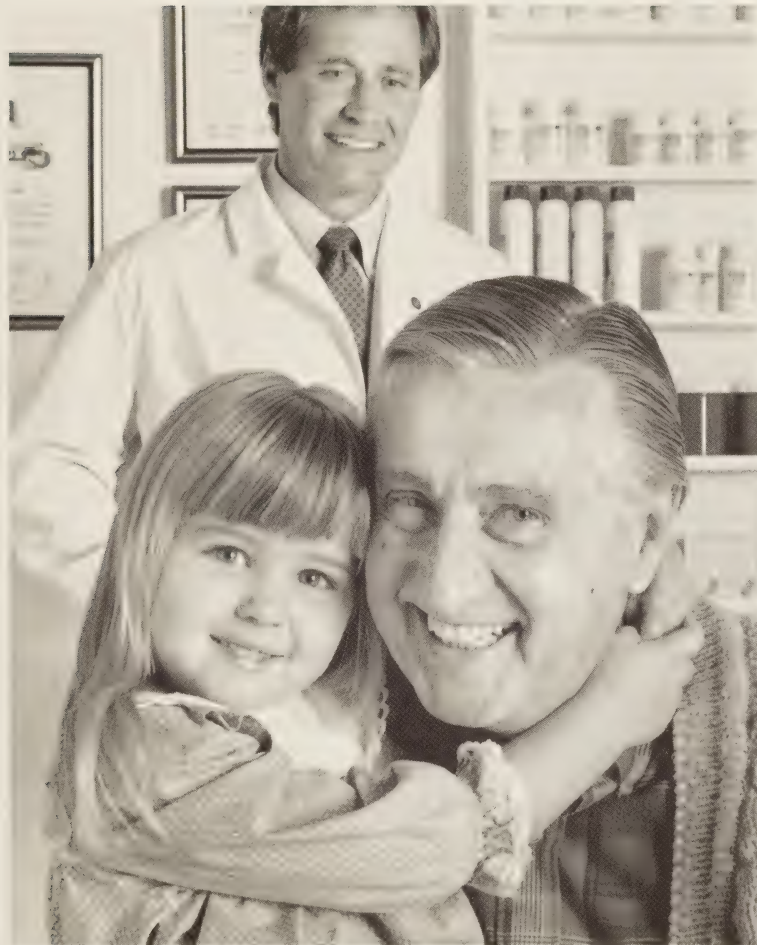
Cost Basis:	Acquisition
Dispensing Fee:	\$3.20
Method of Billing:	UCF/tape/on-line
Dependent Age:	Most 19/25, some have no limit
Refills Allowed:	1 year or by law
Generics Required:	Federal MAC list unless DAW
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Most, 34 days supply or 100 doses
Maintenance List:	Some plans have 100 or 200 days supply lists.
Maryland Rx's Only:	Yes
Processor:	Medimet

#### Special Items

Smoking Cessation:	Pre-authorization
Rogaine:	Pre-authorization
Retin A:	Yes
Cyclosporine:	Yes
Retrovir:	Pre-authorization
Fertility:	Yes
Rx Vitamins:	Yes
Anorectics:	Yes
Contraceptives:	Yes
Diaphragms/Devices:	No, for most plans
Insulin:	Yes
Syringes:	Yes, for some plans only
Diabetic Supplies:	No
Injections:	Yes, if self-administered

*Notes:* Some programs have copays determined by price. For example, Sears has a \$10 copay for prescriptions costing less than \$75.00 with a \$15.00 copay for prescriptions greater than \$75.00.

# We believe, like you do, that it's the little things in life that count.



As a pharmacist, you have the opportunity to really appreciate the little things that make life worth living every single day. The simple smile of trust from a customer, the infectious giggle from a child. The miraculous fact that one small pill can help keep a person healthy.

At Marion Merrell Dow, we know just how much you appreciate the little things. That's why we do them with each and every one of our products, to assure that the quality is there each and every time you dispense them.

Our quality control is, in fact, a series of little things, a special pattern of checkpoints that takes place before, during, and even after the manufacturing process.

For the best in pharmacy and in life, it's definitely the little things that count. That's why you can always count on Marion Merrell Dow.



MARION MERRELL DOW INC.

**PRESCRIPTION PRODUCTS DIVISION**

KANSAS CITY, MO 64114

Your prescription for better business.

# NPA

National Prescription Administrators  
1200 Route 46  
Clifton, New Jersey 07013  
(800) 576-7813

Cost Basis:	AWP
Dispensing Fee:	Lower of U/C, fees vary
Method of Billing:	UCF/tape/on-line
Dependent Age:	Most less than 19
Refills Allowed:	Some plans allow only 6 months, others allow up to one year
Generics Required:	Some plans split copays, *PPD
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Greater of 34 days supply or 100 doses
Maintenance List:	No
Maryland Rx's Only:	Yes
Processor:	NPA

## Special Items

Smoking Cessation:	No for most plans
Rogaine:	No for most plans
Retin A:	Yes, only up to age 19
Cyclosporine:	Pre-authorization required
Retrovir:	Pre-authorization required
Fertility:	No for most plans
Rx Vitamins:	No for most plans
Anorectics:	No for most plans
Contraceptives:	Yes for plans 1,3
Diaphragms/Devices:	No
Insulin:	Yes
Syringes:	Yes
Diabetic Supplies:	No
Injections:	Yes, for most plans

*Notes:* NPA requires all generics be substituted even if they are not considered equivalent by the Maryland Formulary Committee. If a generic is required and patient requests brand, the patient must pay the difference. NPA pays a \$1.00 compounding fee.

# NPP-PHS

Nationwide Prescription Plans  
Prescription Health Systems  
6025 Slauson Avenue  
Culver City, California 90230-6507  
(800) 421-2342  
(310) 391-1133  
(310) 391-0171 FAX

Cost Basis:	Varies by plan
Dispensing Fee:	Varies by plan
Method of Billing:	UCF/tape/on-line
Dependent Age:	Varies by plan
Refills Allowed:	Varies by plan
Generics Required:	Most plans require
Doctor List:	No
Pre-Authorization:	Varies by plan
Days Supply:	30 day supply, some plans allow the greater of 30 days or 100 doses.
Maintenance List:	Yes, for most plans
Maryland Rx's Only:	Yes
Processor:	PHS for its own NPP network

## Special Items

Smoking Cessation:	Varies by plan
Rogaine:	Varies by plan
Retin A:	Varies by plan
Cyclosporine:	Varies by plan
Retrovir:	Varies by plan
Fertility:	Varies by plan
Rx Vitamins:	Varies by plan
Anorectics:	Varies by plan
Contraceptives:	Varies by plan
Diaphragms/Devices:	Varies by plan
Insulin:	Varies by plan
Syringes:	Varies by plan
Diabetic Supplies:	Varies by plan
Injections:	Varies by plan

*Notes:* PHS NPP program pays monthly. Many plans have a maximum 21 day supply of medication; thereafter the patient must use Baxter's mail order program. Maryland pharmacies who use PHS for Blue Cross, Columbia FreeState, Care First, etc. are already included in the PHS NPP network.

# PAID Prescriptions

PAID Prescriptions  
Post Office Box 100  
Fairlawn, New Jersey 07410-9900  
(800) 922-7890  
(800) 922-1557

Cost Basis:	Varies, many plans ACQ
Dispensing Fee:	Varies
Method of Billing:	UCF/tape/on-line
Dependent Age:	Most plans 19/23
Refills Allowed:	By law
Generics Required:	Many plans use FDA list, *PPD
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Most 34 days supply. Some plans allow 100 doses.
Maintenance List:	No
Maryland Rx's Only:	Most plans
Processor:	PAID

## Special Items

Smoking Cessation:	No, for most plans
Rogaine:	No, for most plans
Retin A:	Some plans
Cyclosporine:	Some plans
Retrovir:	Some plans
Fertility:	Some plans
Rx Vitamins:	Some plans
Anorectics:	Some plans
Contraceptives:	Some plans
Diaphragms/Devices:	Only for a few plans
Insulin:	Yes, for most plans
Syringes:	Some plans
Diabetic Supplies:	Some plans
Injections:	Some plans

*Notes:* PAID provides a chart with plan rules. Many plans do not cover DESI drugs.

# PCS

PCS, Inc.  
Post Office Box 52115  
Phoenix, Arizona 85072-2115  
(602) 391-4717  
(800) 345-5413 *Recap Only*

Cost Basis:	Varies by plan
Dispensing Fee:	Varies by plan
Method of Billing:	On-line
Dependent Age:	RECAP verification
Refills Allowed:	Varies
Generics Required:	Some plans split copays, *PPD
Doctor List:	No
Pre-Authorization:	Varies by plan
Days Supply:	Varies
Maintenance List:	Yes
Maryland Rx's Only:	Yes
Processor:	PCS

## Special Items

Smoking Cessation:	Verify through RECAP
Rogaine:	No
Retin A:	Verify through RECAP
Cyclosporine:	Verify through RECAP
Retrovir:	Verify through RECAP
Fertility:	Verify through RECAP
Rx Vitamins:	Verify through RECAP
Anorectics:	Verify through RECAP
Contraceptives:	Verify through RECAP
Diaphragms/Devices:	No
Insulin:	Verify through RECAP
Syringes:	Verify through RECAP
Diabetic Supplies:	Verify through RECAP
Injections:	Verify through RECAP

*Notes:* Some groups have an annual deductible. Refer to "State Employees" section for details on PCS' program for the Maryland Department of Personnel.

## PDI

Prescription Drugs, Inc.  
1111 Cherry Hill Road  
Baltimore, Maryland 21225  
(410) 354-1466

Cost Basis:	AWP
Dispensing Fee:	\$ 2.75
Method of Billing:	UCF/tape
Dependent Age:	19/23
Refills Allowed:	By law
Generics Required:	Yes for some plans. Some plans split copays.
Doctor List:	No
Pre-Authorization:	> \$200
Days Supply:	Greater of 34 days supply or 100 doses
Maintenance List:	No
Maryland Rx's Only:	Yes
Processor:	PDI

### Special Items

Smoking Cessation:	Yes, for some plans only
Rogaine:	Yes
Retin A:	Yes, for acne only
Cyclosporine:	Pre-authorization required
Retrovir:	Pre-authorization required
Fertility:	Pre-authorization required
Rx Vitamins:	Yes
Anorectics:	Yes
Contraceptives:	Some plans up to 3 cycles. 1 copay per pack.
Diaphragms/Devices:	No
Insulin:	Yes, up to 3 vials
Syringes:	Yes, up to 30 with insulin only
Diabetic Supplies:	Some plans
Injections:	No

*Notes:* PDI did not respond to our 1992 survey. This information is reprinted from the 1991 directory.

## Penn Scripts

c/o General Computer Corporation  
2045 Midway Drive  
Twinsburg, Ohio 44087  
(800) 544-6688

Send UCF forms to:  
Penn Scripts  
508 North Third Street  
Harrisburg, Pennsylvania 17101

Cost Basis:	AWP
Dispensing Fee:	Lower of U/C or \$2.75 to \$3.25
Method of Billing:	UCF/tape/on-line
Dependent Age:	Covered if name on card.
Refills Allowed:	By law.
Generics Required:	*PPD
Doctor List:	No
Pre-Authorization:	No
Days Supply:	Greater of 34 days supply or 100 doses
Maintenance List:	No
Maryland Rx's Only:	Yes
Processor:	Penn Scripts

### Special Items

Smoking Cessation:	No
Rogaine:	No
Retin A:	Yes, only up to age 30
Cyclosporine:	Yes
Retrovir:	No
Fertility:	No
Rx Vitamins:	No
Anorectics:	No
Contraceptives:	Plan A only
Diaphragms/Devices:	No
Insulin:	Yes, paid at cost + 50%
Syringes:	Plan A only
Diabetic Supplies:	No
Injections:	No

*Notes:* There is a \$500/year maximum on some plans. There is no nursing home coverage. There is a 180 day limit for submitting claims. Penn Scripts requires the state license number of the prescriber on the claim form. Penn Scripts did not respond to our 1992 survey. This information is reprinted from the 1991 directory.

## Pru-Care

Prudential Health Care Plan, Inc.  
c/o DPS  
Route 4088, Post Office Box 169052  
Duluth, Minnesota 55816-8220  
(800) 233-8065 *Administration Issues*  
(410) 554-7300 *Pre-authorization*  
(410) 554-7000 *Enrollment*

Prudential Healthcare Plan, Inc.  
2800 North Charles Street  
Baltimore, Maryland 21218

Cost Basis:	AWP-10%
Dispensing Fee:	\$2.00
Method of Billing:	On-line
Dependent Age:	By card
Refills Allowed:	By law
Generics Required:	*PPD, unless DAW
Doctor List:	Yes
Pre-Authorization:	Some drugs, see formulary.
Days Supply:	34 days supply
Maintenance List:	No
Maryland Rx's Only:	No
Processor:	DPS for PruCare

### Special Items

Smoking Cessation:	Pre-authorization
Rogaine:	No
Retin A:	Yes, for acne only
Cyclosporine:	Yes
Retrovir:	Pre-authorization
Fertility:	Pre-authorization
Rx Vitamins:	Prenatals and some folic acid
Anorectics:	No
Contraceptives:	Some plans, 3 months for 3 copays
Diaphragms/Devices:	Yes, for some plans
Insulin:	1 vial for 1 copay
Syringes:	For insulin only
Diabetic Supplies:	No
Injections:	Pre-authorization

*Notes:* PruCare, formerly the Johns Hopkins Health Plan, does not cover nystatin powder, Yocon or Hydergine. Pre-authorization is required for Mevacor, amphetamines, nimopine, Videx, smoking cessation products, Retrovir, Synarel and all injectables. Some subscribers have only contraceptive coverage.

## State Employees Program

PCS, Inc.  
Post Office Box 52115  
Phoenix, Arizona 85072-2115  
(800) 345-5413 *RECAP only*  
(602) 391-4717

Cost Basis:	AWP-8%
Dispensing Fee:	\$3.75
Method of Billing:	On-line
Dependent Age:	RECAP Verification
Refills Allowed:	1 year
Generics Required:	State Formulary
Doctor List:	No
Pre-Authorization:	Some drugs, see formulary.
Days Supply:	34 days supply
Maintenance List:	Yes, up to 100 days supply
Maryland Rx's Only:	Yes
Processor:	PCS

### Special Items

Smoking Cessation:	Pre-authorization
Rogaine:	No
Retin A:	Yes, for acne only
Cyclosporine:	Yes
Retrovir:	Yes
Fertility:	Pre-authorization only
Rx Vitamins:	No
Anorectics:	No
Contraceptives:	Yes, up to a 6 month supply
Diaphragms/Devices:	Norplant only, pre-authorization
Insulin:	Yes, up to 4 vials
Syringes:	No
Diabetic Supplies:	No
Injections:	Yes

*Notes:* Copays will vary by brand/generic, formulary/non-formulary/Select or Non-Select pharmacy. DESI drugs are not covered. Growth hormones are permitted only on pre-authorization.

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# Important figures in diabetes care



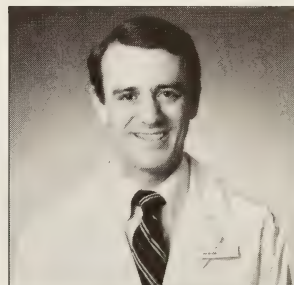
Diabetes is the **No. 7** cause  
of death in the US<sup>1</sup>

---



Diabetes is the **No. 1** cause of new  
blindness in persons aged 20-74<sup>1</sup>

---



Pharmacists see patients with diabetes  
**5** times more often than do physicians.  
These customers spend 3 to 8 times more  
annually in the pharmacy than persons  
without diabetes.<sup>2</sup>

---



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1. *Diabetes Surveillance, 1980-1987*. Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes*. Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

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## Dickinson's Pharmacy

Jim Dickinson

*FDA's Kessler warns you.* Within five years, the big debate about mail-order versus retail pharmacy will be over and the winner will be known. The brilliant young physician-lawyer who heads FDA, David A. Kessler, says he knows the winner already -- the pharmacies that most ably provide what the public wants most from pharmacy: drug information.

Kessler has committed FDA's support, through upgraded package inserts and moral leadership, to spurring private-sector, voluntary supply of this information.

By coincidence, even as Kessler was announcing this, USP honored a single mail-order drug company (Medco) for reaching three times as many patients as all independent pharmacies combined (30 million USP patient information leaflets distributed versus 10 million!).

As a father of two young children, Kessler often goes into pharmacies to get prescriptions filled. Not once, he says, has he been counseled by a pharmacist about the medications dispensed.

---

***As many as 85% of patients are reluctant to ask questions.***

---

In the December 5 issue of the *New England Journal of Medicine*, Kessler chided both his own profession and pharmacy for not doing a better job of disseminating drug information, especially risk information (which a CBS study in 1984 found is what patients want most).

Physicians "need to reexamine the amount of information they give their

patients and the way they deliver it," Kessler wrote. "In addition, they need to acknowledge that pharmacists should have a larger role in patient education and advise their patients to expect counseling when they fill their prescriptions.

"Pharmacists should reinforce the instructions of physicians by direct counseling. Since as many as 85 percent of patients are reluctant to ask questions, the pharmacist should initiate the conversation."

Kessler also want patients to be given a printed information sheet as well, and he endorses the very USP/DI sheets that Medco's National pharmacies were rewarded for disseminating. Ideally, he told this columnist, USP/DI -- or other -- information could be printed out for each patient on the pharmacy computer from already marketed software (to order from USP, call (800) 227-USPC).

Retail pharmacies have an advantage here. Former Medco employees have testified repeatedly as to how USP's leaflets are abandoned in the high-speed rush to get those prescription packages out the mail room door. While Medco may well have purchased 30 million leaflets from USP, such testimony suggests that fewer have actually gone out to Medco prescription recipients (we hesitate to call them "beneficiaries").

Individual, one-at-a-time print-outs -- perhaps customized to bear the patient's own name at the top -- dispensed with the physical medicine and the pharmacist's oral words of advice represent the ideal solution to the patient information problem, in Kessler's view.

"People want information, they deserve information," he told us.

"And we have got to give them information in the right kind of format. Advertising is not the right kind of format ... I think the pharmacy community recognizes that it needs to do a better job and wants to do a better job."

Under his direction, FDA is developing a new-look package insert for new drugs that are approved, to incorporate a lay-language patient information section. Unlike the 1980 uproar over FDA written PPIs, it won't be mandatory for pharmacists to dispense these new inserts.

---

***"Unless the pharmacy community [counsels]... the world will pass them by."***

---

"We already have it," Kessler said. "If you look at the package insert for Prozac, it has a section buried in paragraph 55, 'Information for Patients'. Well perhaps we need to have a separate stand-alone section that the pharmacist can use as a prestanding format."

That would accommodate only new drugs, as part of the FDA approval process. Established drugs could be handled by FDA on a class basis, or left with private-sector marketers such as USP. FDA hasn't made up its mind about that.

Kessler senses "considerable interest" in patient information among manufacturers, who see better patient compliance yielding both product liability benefits for themselves as well as increased sales.

## Dickinson's Pharmacy

### Continued

In his jawboning with pharmacy interests, Kessler has been blunt. He has told them, he says, that "unless the pharmacy community does this, my sense is the world will pass them by.

"What is the prime issue today? You have a profession that is to some extent in search for its own identity. And my sense is that this is where the future of profession needs to focus, because the alternative is the European system of unit packaging with patient information incorporated by the manufacturer. Again, what we are talking about is *counseling*, we are not talking about just information sheets.

This young vital FDA commissioner has taken just 12 months in Washington to capture both the attention and mindful respect of the health establishment. Without showing any partisanship, he is displaying a fervent advocacy of one-on-one, traditional pharmacy. His comments give the profession five years to answer the challenge facing it. But he cannot know for sure if that's what the marketplace will really allow. Pharmacy should not dally.

"With the price of a personal computer being what it is and a printer being what it is, I think it is good business," Kessler told us. "Certainly it is good business for the pharmaceutical firms. It's compliance, the more people know about their drugs the greater likelihood they're willing to take their medicines and be in compliance. That translates into sales for everybody."

This feature is presented on a grant from Dickinson's Pharmacy -- *The Independent Voice*, a professionally stimulating 8-page monthly newsletter available from Ferdic, Inc., PO Box 848, Morgantown, WV 26507-0848 at an annual subscription fee of \$45. Opinions expressed herein are those of the author and do not constitute official positions or policy of the Maryland Pharmacists Association.

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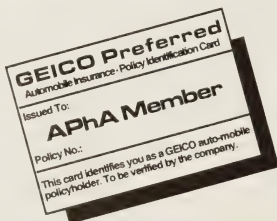
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# Classified

"Rx" LICENSE PLATES are still available through MPHA. When you receive your license renewal form, contact Mary Ann at (410) 727-0746 for details. The plates say "Pharmacist Association" in addition to "RX" and the number. This offer is open only to members and their immediate family.

**THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION**, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (410) 358-7036.

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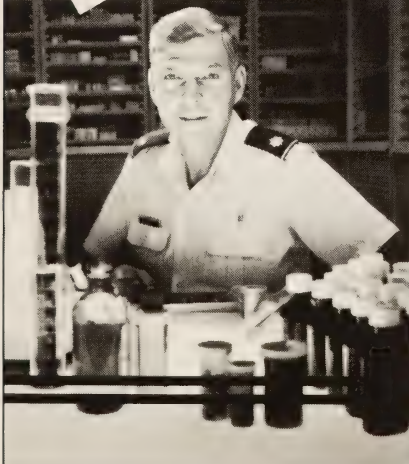
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# *The Maryland Pharmacist*

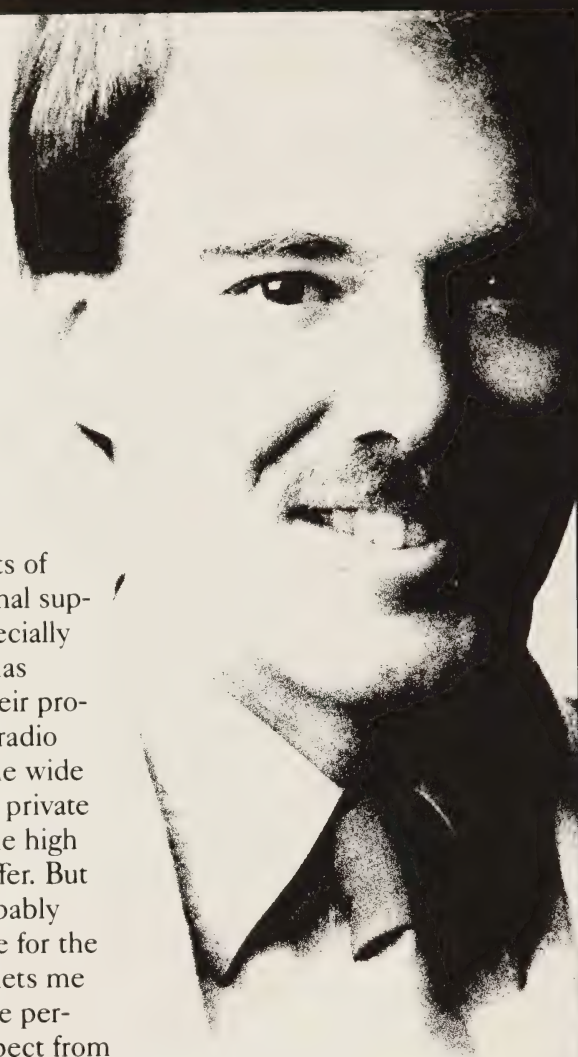
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APRIL 1992

NO. 4



*Hypertension Awareness Month*  
*May 1992*



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belong to  
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There must  
be a reason.**

**I**n fact, there are lots of reasons. Promotional support for example, especially now that McKesson has added cable TV to their program of circulars and radio spots. Then there's the wide selection of Valu-Rite private label products, and the high profit margins they offer. But most pharmacies probably sign on with Valu-Rite for the same reason I did: it lets me give my customers the personal service they expect from an independent, along with the low prices of a national chain. That's a combination that just can't be beat.”

*Scott Rickards*

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# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association  
650 West Lombard Street, Baltimore, Maryland 21201-1572

April 1992

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Number 4

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## President's Commentary

Ilene Zuckerman, Pharm.D.



**The question for pharmacists is not *whether* they will change, but *how* they will change to maintain their ability to make a satisfactory living by practicing pharmacy.<sup>1</sup>**

We spend an enormous amount of time, both as individuals and as organizations, dealing with third-party issues. Each plan has different rules, different reimbursement structures. Last month's issue of *The Maryland Pharmacist* will give you guidance with the third-party reimbursement maze. Today's reimbursement is vitally important to the economic survival of pharmacy; however, at the same time, we must look beyond today, into the future of our profession. And, this future encompasses the professional lifespan of most pharmacists practicing today.

We all know that technology, public policy and the health care system are changing pharmacy practice. Change **will** occur. Is the pharmacy profession going to be reactive or proactive? For example, technology already exists for mass robotic prescription dispensing. This technology is more efficient and more accurate than traditional dispensing by pharmacists and technicians. What will be our professional role once robotic dispensing is widely used by chain drug stores and hospitals?

Professional pharmacy organizations have a responsibility to develop and disseminate our professional responsibilities. Hepler and Strand<sup>2</sup> have outlined a philosophy of practice that meets the needs of the public and consumers of health care, and at the same time increases our professional responsibility. *Pharmaceutical care* is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are: cure of a disease, elimination or reduction of a patient's symptomatology, arrest or slowing of a disease process, or prevention of a disease or symptomatology. In this context, pharmaceutical care means that the pharmacist designs, implements and monitors a therapeutic plan that will produce the therapeutic objective. Provision of safe and effective drug *products* is one component of pharmaceutical care; pharmaceutical care provides safe and effective drug *therapy*.

The success of the pharmaceutical care concept lies with individuals. Individuals practitioners practice pharmacy, not pharmacy organizations. Each of us must decide for ourselves how we want to practice pharmacy. We must look beyond our self-interests, and focus instead on our public responsibility. Drugs are the most common therapeutic intervention in health care. We have a responsibility to our patients to maximize their drug therapy outcomes; that is, to practice pharmaceutical care. Once we accept this philosophy, we can move on to implementation.

Each of us has stumbled through our teenage years; similarly, there are obstacles we must cross to reach our professional adulthood. It is typical to hear pharmacists discuss the question, "What are the barriers to incorporating a pharmaceutical care system into my practice?"

Perhaps the most frequently discussed barrier is, "How can I provide

pharmaceutical care if there is no mechanism for reimbursement?" Finding the resources to practice pharmaceutical care must occur *after* pharmaceutical care has become a standard of practice within the profession, or, after the benefit of pharmaceutical care is perceived by the consumers of pharmaceutical care (including both individual patients and third-party reimbursers). This is where professional pharmacy organizations can help.

The professional pharmacy organization can facilitate the development and implementation of practice standards. Organizations can set up demonstration projects that implement pharmaceutical care. Indeed, MPhA is developing practice standards and assisting individual practitioners with incorporating pharmaceutical care into their practice. Once the demand is created, and there are pharmacists that have demonstrated the value of pharmaceutical care system, then professional organizations can pursue reimbursement. However, the organizations cannot practice pharmaceutical care; you must do that.

Another frequently discussed barrier is the issue of competence. Do pharmacy practitioners have the necessary skills, knowledge and attitudes to design, implement, and monitor a pharmaceutical care plan? It is important to distinguish competence from confidence. Just because one is confident that he can practice pharmaceutical care, does not necessarily imply competence. Conversely, a lack of confidence is often the real barrier in some individuals.

Educational institutions can provide the necessary environment to achieve competence. Faculty of the University of Maryland School of Pharmacy have agreed to do their part by providing an educational model that will meet these future needs. One result of their efforts is the development and implementation of a new course for practitioners, "Introduction to Pharmaceutical Care in Community Practice." Currently, 15 pharmacists are enrolled. The move to an entry-level Doctor of Pharmacy curriculum will assure competency for future generations of pharmacists. For individuals who want to pursue further development of pharmaceutical care skills, the non-traditional doctoral program will be available. This program is designed for practicing pharmacists to meet the schedule, economic barriers, and educational needs of the working pharmacist.

MPhA and other pharmacy organizations in Maryland

are planning a conference on pharmaceutical care and its impact on pharmacy practice in Maryland. Presumably, issues relating to practice standards, reimbursement, and competency will be discussed. A desirable outcome of the conference would be a consensus among the professional pharmacy community about the acceptance and implementation of pharmaceutical care in Maryland.

It is time for us to accept responsibility for and direct our professional future. If we are successful, then *The Maryland Pharmacist* "Third Party Directory" of the future will discuss the reimbursement of pharmaceutical care rather than the reimbursement of the pharmaceutical product. ■

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## Calcium Channel Blockers

### *A Review of an Ever Growing Therapeutic Class*

*Kathrin Kucharski, Pharm.D.*

Calcium channel blockers -- will it ever end? Over the last year, three new calcium channel blockers were released onto the market, bringing the total number of currently available products in this class to eight. Not only are there eight different chemical entities, but several of these agents are also available in sustained release formulations. To add to the confusion, not all of the calcium channel blockers share the same indications.

So the question is: are there any differences between calcium channel blockers and are these differences clinically significant? The answer is yes. There are differences between these products -- some of which are clinically significant -- some of which are not and for some of the differences, the clinical importance is yet to be determined.

The calcium channel blockers were first synthesized in

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*All calcium channel blockers are well absorbed orally and have a significant first pass effect*

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the late 1950's and were investigated as antihistamines. Their peripheral vasodilatory effects were later observed and thus their use as antihypertensive agents was pursued. Later still, the effect of these agents on myocardial muscle, the cardiac conduction system, and coronary vessels led to their use as antiarrhythmic and anti-anginal drugs.

Calcium channel blockers block the influx of extracellular calcium ions across the membranes of myocardial cells, the cardiac conduction system, and vascular smooth muscle cells. This blockade affects primarily the heart and coronary, cerebral and peripheral vessels. Calcium blockade of the myocardial cells results in a decrease in the force and rate of myocardial contraction while calcium blockade of the vascular smooth muscle cells results in vasodilation. The decrease in the rate and force of myocardial contraction and the vasodilation provide the basis for the anti-anginal and anti-hypertensive effects of these drugs. In addition, the anti-arrhythmic effect comes from the calcium blockade of the cardiac conduction system. The most significant difference between the calcium channel blockers is their

primary site of action. The calcium channel blockers have varying selectivity for these different sites of action which then determines their pharmacological activity. The comparative pharmacological effects of the currently available calcium channel blockers are depicted in Table 1.

The site of the pharmacological effects of the calcium channel blockers determines the indication of the agent. The approved indications of these agents are listed in Table 2.

All of the calcium channel blockers are well absorbed orally and have a significant first pass effect. They all have a relatively short half-life, thus requiring three to four times daily dosing for the immediate release forms. Several of these agents are available in a sustained release form in order to decrease the dosing requirements, provide more stable blood levels throughout the day, and maximize compliance. Dosing information for these products is indicated in Table 3.

The calcium channel blockers differ not only in their indication but also differ significantly in their side effect profile. Again, the site of pharmacological activity determines not only the indication but also the side effect profile.

**VERAPAMIL** (Calan, Isoptin, Calan SR, Isoptin SR, Verelan) Verapamil causes moderate vasodilation of both the peripheral and coronary vessels. It also decreases myocardial contractility and slows conduction across the AV node. It is an excellent anti-anginal, anti-arrhythmic and antihypertensive agent. The sustained release preparations are officially indicated for use in hypertension only. Because of the negative effect on myocardial contractility and the AV node, verapamil may cause an exacerbation in congestive heart failure, worsening of pulmonary edema, significant AV blockade and bradycardia. Some of the central nervous system side effects include dizziness, insomnia, confusion, and sleepiness. The geriatric population may be particularly sensitive to the central nervous system side effects. Other very commonly reported adverse effects are hypotension and constipation.

Agent	Peripheral Vasodilation	Coronary Vasodilation	Heart Rate	Myocardial Contractility	AV Node Conduction	Cerebral Vasodilation
Verapamil	++	++	+/-	-	--	+
Diltiazem	+	+++	-	none	-	+
Nifedipine	+++	+++	+	-/+	none	+
Nicardipine	+++	+++	+ / 0	none	none	+
Felodipine	+++	++	+ / 0	none	none	none
Isradipine	+++	+++	+ / 0	none	none	none
Nimodipine	+	?	none	none	none	+++
Bepridil	+	+++	-	-	--	-

Table One

*NIFEDIPINE* (Adalat, Procardia, Procardia XL), *NICARDIPINE* (Cardene), *ISRADIPINE* (DynaCirc), *FELODIPINE* (Plendil) These agents are all in the same chemical class and act primarily as vasodilators. They have minimal effect on myocardial contractility and the cardiac conduction system. They are excellent anti-anginal and antihypertensive agents. They are all approved for the treatment of hypertension except, interestingly, the immediate release form of nifedipine. The immediate release form of nifedipine is often used, though, for the treatment of hypertension and hypertensive crises. The immediate release form of nifedipine is a liquid filled capsule. The capsule may be punctured with a needle and the liquid squirted inside the mouth or the capsule may be chewed for more immediate release of the drug in the case of hypertensive crises. The nifedipine liquid is very light sensitive, so care must be taken that the liquid goes directly into the mouth as quickly as possible. Some of the generic immediate release products available have very hard capsules and thus may not be easily punctured or chewed. Procardia XL is a novel dosage formulation. As with any sustained release preparation, it should not be crushed. Patients should be told that the empty tablet that once contained the drug may be found in their stools. Felodipine and isradipine do not have an indication for the treatment of angina at this time. Felodipine is available only in a sustained release preparation. There does not appear to be any significant difference in the efficacy of the different agents approved for hypertension or for angina at this time. These agents, due to their peripheral

vasodilatory effects, may cause significant peripheral edema, flushing, reflex tachycardia, orthostatic hypotension, and headache. Some studies suggest that nicardipine, felodipine, and isradipine may cause less side effects than nifedipine. There is a cost difference between some of these agents, thus cost may be the deciding factor for determining which of these agents is selected.

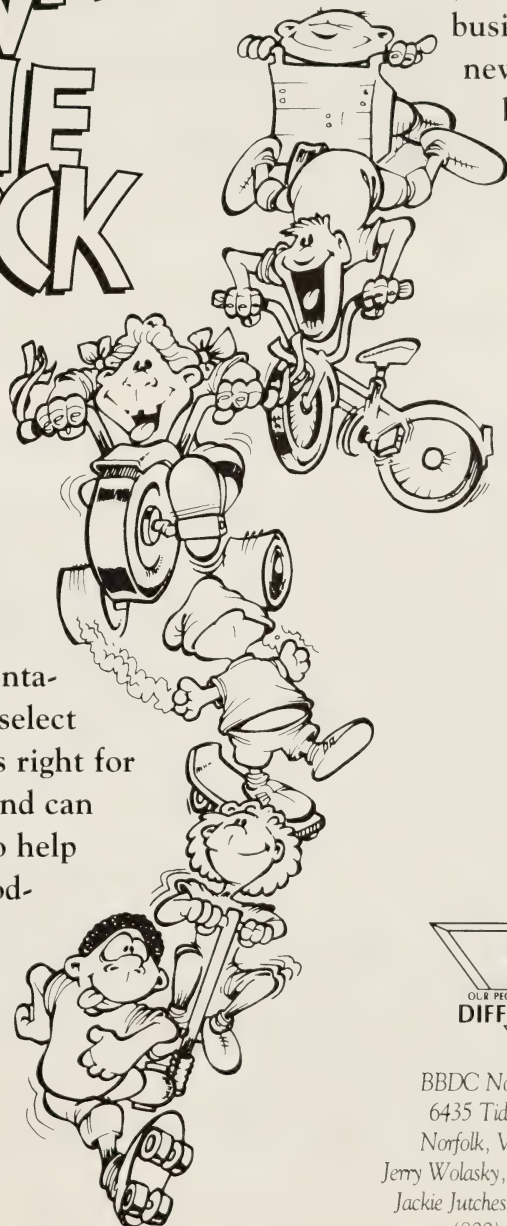
*DILTIAZEM* (Cardizem, Cardizem SR, Cardizem CD) Diltiazem shares some of the properties of both verapamil and the nifedipine like agents. It does not have as potent effects on the heart or the peripheral vasculature but is still an excellent anti-anginal and antihypertensive agent. It may also be used for atrial fibrillation or flutter. The sustained release preparation is approved for hypertension only but is also used as an anti-anginal agent. Cardizem SR is usually administered twice daily. Recently a new product Cardizem CD was introduced as a once a day product. Diltiazem also shares the side effects of verapamil and the nifedipine like agents but not usually to the degree that those agents can.

*NIMODIPINE* (Nimotop) Nimodipine is in the same chemical class as nifedipine but is not indicated for hypertension or angina. It is indicated for the management of recent subarachnoid hemorrhages. It decreases the severity of associated delayed ischemic neurological deficits and also prevents aneurysm rerupture. Since nimodipine has very little effect on the heart or the peripheral vasculature, it has minimal effect on blood pressure. Common side effects include flushing, fluid retention, and constipation.

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Agent	Indication
Verapamil	Supraventricular arrhythmias, angina, hypertension.
Diltiazem	Atrial fibrillation/flutter, angina, hypertension.
Nifedipine	Angina, hypertension.
Nicardipine	Angina, hypertension.
Isradipine	Hypertension.
Nimodipine	Subarachnoid hemorrhage.
Felodipine	Hypertension
Bepridil	Angina

*Table Two*

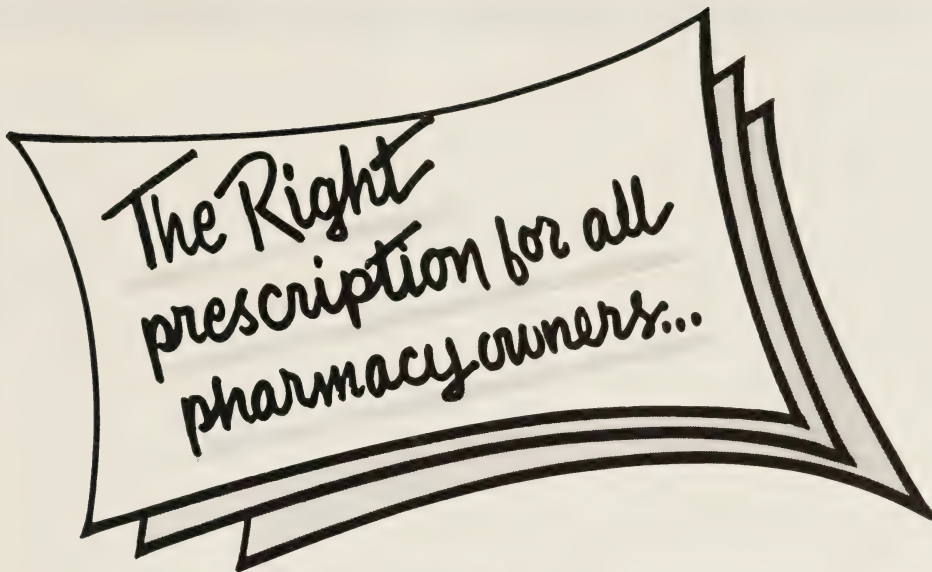
**BEPRIDIL** (Vascor) Bepridil is indicated for the treatment of angina. This agent is considered a second or third line anti-anginal agent due to the black box warning regarding possible induction of potentially life threatening arrhythmias. Ventricular tachycardia and fibrillation and torsades de pointes have occurred in 1% of patients treated with this agent in the United States. These

proarrhythmic effects may be enhanced by hypokalemia and concomitant use of other drugs that prolong the Q-T interval such as digoxin, quinidine, procainamide, and tricyclic antidepressants. Other adverse effects may include dizziness, headache, nausea, and diarrhea.

There are several other calcium channel blockers in the pipeline and new uses for these agents such as prophylaxis for migraine headaches, Raynaud's syndrome, asthma, nocturnal leg cramps and congestive heart failure are under investigation. So the answer to the question is no. It will never end. ■

Immediate Release Verapamil	40 - 120 mg every 8 hours
Sustained Release Verapamil	240 - 480 mg every 24 hours
Immediate Release Diltiazem	30 - 90 mg every 6 hours
Sustained Release Diltiazem	SR: 60 - 120 mg every 12 hours CD: 180 - 300 mg every 24 hours
Immediate Release Nifedipine	10 - 30 mg every 6 hours
Sustained Release Nifedipine	30 - 90 mg every 24 hours
Felodipine	5 - 20 mg every 24 hours
Isradipine	2.5 - 10 mg every 12 hours
Nicardipine	20 - 40 mg every 8 hours
Nimodipine	60 mg every 6 hours for 21 days
Bepridil	200 - 400 mcg every 24 hours

*Table Three*



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## ACE Inhibitors

It is accepted widely that antihypertensive therapy can reduce significantly patient morbidity and mortality resulting from high blood pressure. But hypertension is often a silent disease. Patients who are asymptomatic find it difficult to accept therapeutic changes in lifestyle or drug treatment, especially when the treatment regimen is complex and accompanied by unpleasant side effects. Poor compliance often follows, and the success of therapy is compromised. Angiotensin converting enzyme (ACE) inhibitors not only are effective in the reduction of blood pressure, they also may improve patient compliance because they are associated with few side effects. A third generation of ACE inhibitors promises even greater compliance.

### Inhibition of the Renin-Angiotensin-Aldosterone System

ACE inhibitors lower blood pressure through the suppression of the renin-angiotensin-aldosterone system (RAS). RAS has long been recognized as an important contributing factor in the regulation of vascular tone and sodium excretion.

Physiologically, this hormonal system protects against volume depletion by releasing renin in response to volume and sodium loss. Renin is an enzyme secreted from the kidney and acts upon angiotensinogen, a globulin substrate or plasma protein.

The product of the action of renin on angiotensinogen is a decapeptide call angiotensin I. While angiotensin I has no biological activity, it is converted by the angiotensin converting enzyme to angiotensin II, one of the most powerful known vasoconstrictors.

In addition to its direct acting as a vasoconstrictor, angiotensin II also causes sodium retention through stimulation of aldosterone release and direct action on sodium reabsorption by the kidney.

The angiotensin converting enzyme is identical to kininase II, the enzyme responsible for the degradation of bradykinin, a local mediator of vasodilation. Thus, in addition to activating a powerful vasoconstrictor (angiotensin II), the enzyme also neutralizes a potent vasodilator (bradykinin).

By inhibiting the angiotensin converting enzyme, ACE inhibitors prevent the formation of angiotensin II. Lower angiotensin II levels result in decrease release of adrenal aldosterone and promote sodium and water excretion.

Thus, ACE inhibitors reduce blood pressure both by direct vasodilating effect and by reducing vascular rigidity due to limited sodium and water in vessel walls.

### ACE Inhibitors vs. Other Antihypertensive Agents

ACE inhibitors compare favorably with thiazide diuretics, beta blockers, and calcium channel blockers in blood pressure reduction. Their antihypertensive activity, however, is not accompanied by many of the side effects associated with these other agents. Specifically, ACE inhibitors do not cause the rebound tachycardia seen with arteriolar dilators; the negative inotropic effect, sinus and AV nodal suppression, or bronchospastic and vasospastic effects of beta blockers, or the biochemical imbalances linked with diuretics.

Consequently, ACE inhibitors are appropriate in the treatment of hypertension in patients with concomitant conditions such as diabetes mellitus, congestive heart failure, hyperlipidemia, gout, asthma, heart block, and peripheral vascular disease. In addition, some of the disturbing quality-of-life symptoms such as drowsiness, fatigue, and impotence, which are often seen with other antihypertensive agents, are seen to a lesser extent with ACE inhibitors.

### The Development of Newer ACE Inhibitors

The first orally effective ACE inhibitor, captopril, was introduced in 1976. It has a short half-life (2 hours) and therefore has to be taken two or three times per day. The absorption of the drug is reduced by 30 percent to 40 percent if food is in the gastrointestinal tract.

Consequently, new research focused on the development of an ACE inhibitor with a longer duration of action. A second generation of ACE inhibitors was developed that met this criterion.

All of the second generation ACE inhibitors (enalapril, ramipril, fentiapril, fosinopril, benazepril, pentopril, perindopril, cilazapril, and quinapril) are prodrugs -- that is, they must be metabolized before the active substance can take effect. With enalapril, the first of this generation to be introduced, the de-esterification produces the active metabolite enalaprilat. Enalapril reaches a peak blood level about one to one-and-a-half hours after dosing, while enalaprilat achieves a peak level three to four hours postdose. This prolonged duration of action means that enalapril can be used once daily for many, but not all, patients to control hypertension.

### The Future of ACE Inhibitors

The efficacy of ACE inhibitors in the treatment of hypertension has been well established in the years since the introduction of captopril. Research has continued to demonstrate the ability of this class of drugs to treat cardiovascular disease, and prevent its progression. Studies are under way to evaluate the ability of ACE inhibitors to regress left ventricular hypertrophy in hypertensive patients, prevent LV dilatation postinfarction, as well as to retard decline in renal function in patients with diabetic renal disease. ■

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## Dickinson's Pharmacy

Jim Dickinson

When pharmacists get mad. The world's most respected profession (yes, other countries now show the same rating as U.S. polls) may have earned that title by being slow to anger.

But that doesn't mean that as a group pharmacists never get angry as every single member of the Florida state legislature found in December, when the state pharmacy association's hotline went into high gear.

The law makers got so heavily bombarded -- executive director Rod Presnell estimates each got an average of about 80 calls -- that they had to call the association to plead: "Please call your people off!"

What caused the fuss? The state awarded its government employees' drug program to a contractor (Consultec, Inc.) which in turn directed all prescriptions exclusively to the Eckerd chain.

By mid-January when this column was written, Presnell was delighted with the response from his members, although it was still too close to the holidays to be able to tell what the state would do next.

A key element in the tremendous response was a powerful feature of the Florida hotline -- pharmacists recruited patients to join their protest in direct contacts with legislators' offices.

This did four things. (1) It greatly increased the flow of calls into the legislators' offices. (2) It disabled any reflex the lawmakers may have harbored to belittle the complaints as "just a bunch of druggists sounding off." (3) It signaled an ominous warning that the controversy could spread without limit unless resolved

quickly. (4) It consolidated the pharmacist-patient bond by establishing a political common cause grounded in patient care.

This is the wave of the future.

To the extent that pharmacists have been unsuccessful until now in persuading third-party programs, managed care companies, insurance plans, government agencies and law makers to preserve a fair business climate, Florida's experience suggests this may have been due to a lack of numbers.

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*The weakest link  
in pharmacy's power chain  
is YOU....*

---

The right numbers, that is. Two hundred pharmacists picketing the Blue Cross/Blue Shield office may be impressive on the evening news, but it is a drop in the bucket to a bustling, scurrying, worry-weary world.

Pharmacy wins when it brings patients to its cause. One pharmacist networking this cause among several hundred patients, energizing them to call or write, is exercising true political clout.

Multiply that by several hundred pharmacists, and you have a revolution in the making. Multiply it by several thousand pharmacists, and it's my prediction that no program's adverse policies will be able to withstand the impact.

But the weakest link in this entire power matrix is someone well known to you.

It's the owner of the face you see in the mirror each morning. If you don't reach out and start this, it may not get started.

So what does it take to get you to do this? In my experience, the pharmacist who suddenly finds that 20% of his or her clientele are going to be rolled over into a closed panel program or mail-order will be moved enough to do it.

I get a lot of calls from such pharmacists, but it's almost always too late at that point. When I call the offending program, I almost always find that they had not heard from the pharmacists until after the announcement -- and then all they hear is abuse.

The abuse proves that pharmacists do get mad, but often when they do it's in a closed loop, when hardly anyone's listening.

The simple truth is that the pharmacists who lose this business have not been listening to local employers, or have not even made an effort to establish communications.

What's needed is a longer fuse, a slower burn. Start getting angry early. Plan a measured defense strategy. Pool your resources and your talents in a network with patients. Focus on quality of care, convenience, and patient rights. Reach out and touch someone.

It's the wave of the future.

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This feature is presented on a grant from Dickinson's Pharmacy -- The Independent Voice, a professionally stimulating monthly newsletter available for \$45 a year plus your retail pharmacy's label form Ferdie Inc., P.O. Box 848, Morgantown, WV 26507-0848.

## Drug Information Questions

### *NSAIDs and Hypertension*

*Babette S. Prince, Pharm.D.*

*Roberta L. Brown, Pharm.D.*

*UMAB Drug Information Center*

#### **Drug Information Request**

A 70 year old patient with hypertension has had well controlled blood pressure for the last five years with stable doses of HCTZ and propranolol. She presents today with new prescriptions for these agents as well as for verapamil. She expresses dismay over having to add medication to control her blood pressure. Her only other medication is OTC ibuprofen, of which she takes two tablets three times a day. She began taking this two months ago for arthritic symptoms on the advice of a friend. Could the ibuprofen have contributed to the deterioration of her blood pressure control?

#### **Response**

The antagonism of antihypertensive effects by many nonsteroidal anti-inflammatory drugs (NSAIDs), including ibuprofen, has been well documented.<sup>1,2,3</sup> A proposed mechanism of this effect relates to the renovascular effects of NSAIDs.<sup>4,5</sup> Renal blood flow (RBF) is determined largely by an intricate balance between vasoconstrictor (eg. catecholamines, angiotensin II) and vasodilator (eg. prostaglandins [PGs]) substances in the renal microvasculature. When an excess of vasoconstrictor substances is present, the kidneys respond by producing additional prostaglandins that act locally to restore RBF.

NSAIDs, by inhibiting PG synthesis, can impair the kidney's ability to overcome the effects of vasoconstrictors in a dose related fashion.<sup>4</sup> A sustained reduction in RBF will trigger systemic mechanisms designed to restore it. The most significant of these mechanisms is stimulation of the renin-angiotensin-aldosterone system. When activated, this system results in vasoconstriction and retention of sodium and water. These effects can, in turn, result in blood pressure elevation.

Obviously not everyone who takes a NSAID experiences blood pressure elevations. The true incidence of this effect is not known; however, asymptomatic renal impairment has been reported to occur in up to 18 percent of patients taking prescription strength ibuprofen.<sup>6</sup> Some patients appear to be more sensitive than others to

the renovascular effects of NSAIDs.

The patients at greatest risk are those who have conditions associated with higher levels of renal vasoconstricting substances. These conditions include renal disease, diabetes, atherosclerotic cardiovascular disease (ASCVD), concurrent diuretic use, congestive heart failure, hepatic cirrhosis, sodium depletion, age greater than 60 years, and hypotension.<sup>4,6</sup>

The common denominator of these is their potential to include reductions in RBF. Restoration and maintenance of RBF under these conditions depends primarily upon the ability of the kidney to produce additional quantities of vasodilatory PGs. Administration of a NSAID in this type of individual can result in unopposed vasoconstriction in the kidney, which may then trigger the series of events described above to ultimately result in elevated blood pressure.<sup>5</sup>

In our patient above, self administration of ibuprofen even in OTC doses could be the cause of loss of adequate blood pressure control.<sup>1</sup> She certainly would be at risk for this effect given her diuretic use, advanced age, and possible presence of ASCVD (for which hypertension is a risk factor).

Evidence suggest that various NSAIDs have different extents of renal PG synthesis inhibition.<sup>3,4,7</sup> Often sulindac and nonacetylated salicylates such as salsalate are

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#### *NSAIDs can adversely affect hypertensive control*

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identified as the NSAIDs having the least effects on renal function.<sup>2,4,7</sup> Sulindac is a prodrug converted by the liver to the active sulfide form. Metabolic enzymes in the kidney are able to inactivate sulindac sulfide, possibly preventing the agent from affecting renal PG production to the same extent as other NSAIDs.

Salsalate's renal-sparing effect is proposed to stem from its inherently weak PG-inhibiting abilities relative to other NSAIDs. Caution should be exercised in extrapolating

these pharmacologic properties to patient care; adverse renal effects have been reported even with these NSAIDs, particularly in high risk patients.<sup>4</sup> Although both dose and choice of NSAID play roles in these adverse reactions, its occurrence seems to depend more upon the presence of conditions which increase the kidney's reliance on PGs for maintenance of RBF.<sup>4,5</sup>

Assessing compliance with medications and diet should be the first step in evaluation of the patient's poorly controlled blood pressure. It will also be helpful to know if her physician is aware of the patient's OTC analgesic use. Informing the patient and the physician of the potential impact of ibuprofen on the success of her antihypertensive therapy should be the next step, before additional and perhaps unnecessary treatments are initiated. We would recommend withdrawal of the ibuprofen and prompt assessment of renal function (serum creatinine and blood urea nitrogen levels).

Follow up renal function and blood pressure measurements one to two weeks later will aid in the evaluation since NSAIDs' renal effects are usually reversible and subside with elimination of the drug from the body.<sup>4</sup> If the ibuprofen is believed to be responsible for the patient's increased blood pressure but pain medication is still desired, at least three options are available. These are, in order of preference: use of OTC acetaminophen if anti-inflammatory effects are not necessary; a carefully monitored trial of a renal-sparing NSAID; or reinstitution of ibuprofen at smaller doses with frequent monitoring of renal function and blood pressure. ■

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This month's Drug Information Questions article was written by Tracy Hicks, a Pharm.D. II candidate at the University of Maryland School of Pharmacy. Do you have ideas for another article? If so, contact the UMAB Drug Information Center at (410) 328-7568.



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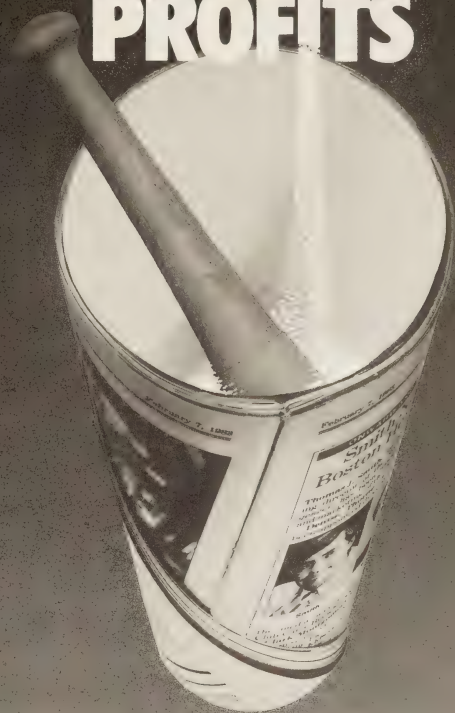
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## Improving Compliance to Hypertension Therapy

Hypertension is a chronic disease that afflicts nearly 60 million Americans and raises their risk of heart attack, stroke, kidney failure, and blindness.<sup>1</sup> Yet half of all people being treated for hypertension discontinue therapy within the first year, according to the National High Blood Pressure Education Program (NHBPEP), an arm of the National Institutes of Health. Of the people who continue to take their medication, nearly one-third do not take it regularly enough to control their hypertension.

Noncompliance is one of the major obstacles to blood pressure control, according to a recent survey of physicians by the American Heart Association (AHA). "Noncompliance" refers to patient behavior that is inconsistent with prescribed therapy. Examples of noncompliance include not taking medication and not making lifestyle modifications as directed. According to the AHA survey, factors involved in noncompliance include poor communication between patients and their physicians, failure to adopt changes in lifestyle, inefficient office follow-up procedures, side effects, and costs of medications and laboratory tests.<sup>2</sup>

The cost to society of noncompliance to drug therapy is considerable. More than 125,000 Americans die each year as a result of noncompliance related to cardiovascular treatments alone.<sup>3</sup> Noncompliance also is directly associated with an increase in physician visits and hospital admission --- at an additional \$8.5 billion annually in health care expenditures.<sup>3</sup>

### Reasons for Noncompliance

Outright refusal to take medication and to make changes in lifestyle describe the compliance problem for only a small number of patients.<sup>4</sup> More commonly, compliance has been found to slip because of a misunderstanding or miscommunication about hypertension, medication and its dosing schedule, and the effects of treatment on patient lifestyle and quality of life.<sup>2,4</sup>

A patient's misconceptions about hypertension often present significant barriers to treatment compliance.<sup>1</sup> According to a recent study at Louisiana State University, some people mistakenly believed that their hypertension was brought on solely by stress and anxiety-producing events. As a result, the study concluded that these people were more likely to stop taking their blood pressure drugs when their level of stress returned to normal.<sup>5</sup>

Misunderstandings about antihypertensive therapy occur for a variety of reasons. Many people with hypertension

are prescribed blood pressure medication concomitantly with medications for other illnesses. The number and types of drugs, as well as their dosing intervals, can change frequently --- often after each physician visit. Generic medications may add to the confusion, as characteristics --- size, shape, color --- vary from one manufacturer to another, making proper identification difficult.<sup>4</sup>

The lifestyle changes required for people with hypertension, such as quitting smoking, losing weight, modifying diet, and exercising regularly, present daily challenges. People can become frustrated and discouraged when they learn that blood pressure control is an ongoing process.<sup>1</sup>

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*Noncompliance with hypertensive therapy costs more than \$8.5 billion annually*

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Also, because high blood pressure often does not cause symptoms, people with hypertension may not feel ill and may forget to follow recommended lifestyle modifications. Some people simply may stop taking their medication, or take it only according to how they feel on a particular day. Side effects from antihypertensive medications, too, may cause some people to stop taking their medication.

### The Health Care Team: Clearing Up The Confusion

Hypertension control is a responsibility that is shared by every member of the health care team --- physicians and other health professional (physician assistants, nurses, pharmacists, and dietitians), as well as the patient, family members, and friends.<sup>2</sup>

Members of the health care team are most effective in helping patients overcome noncompliance from misunderstanding.<sup>4</sup> Effective compliance strategies consider patients' needs, involve them in their treatment, and seek not only to inform but to educate them about hypertension and its treatment. In one study, blood pressure control increased by 28 percent among patients who received just fifteen minutes of counseling in their physicians' offices, compared to a control group of patients who did not receive educational intervention.<sup>1</sup> Another study showed that when educational intervention is followed by family support, a significant increase

(65 percent) in blood pressure control can be achieved, as well as greater patient satisfaction and better overall health. ■

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## Hypertension & Noncompliance

### Hypertension

Hypertension (high blood pressure) afflicts 60 million Americans.

Hypertension often has no symptoms but must be treated. Uncontrolled hypertension raises the risk of heart attack, stroke, kidney failure, and blindness.

Hypertension is controllable with medication and changes in lifestyle, including eating a healthier diet, losing weight, quitting smoking, and exercising regularly.

### Noncompliance

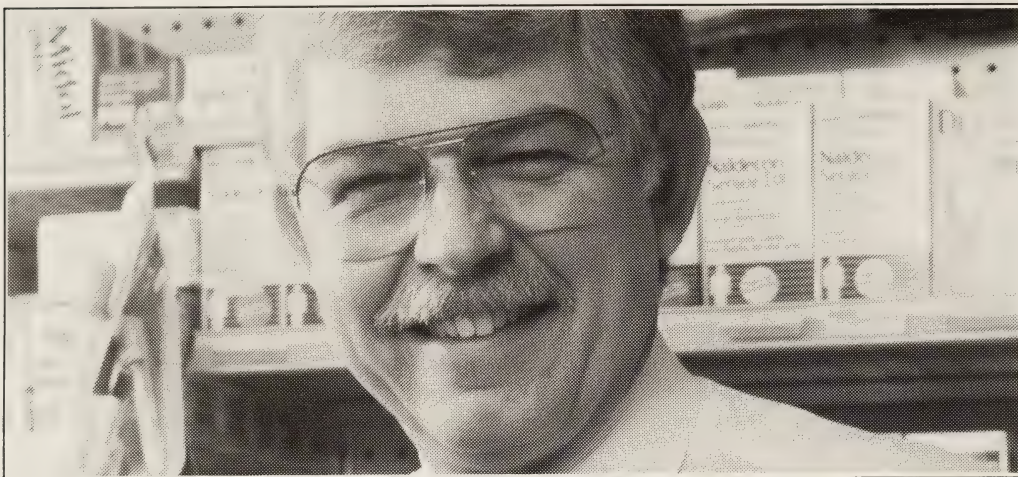
"Noncompliance" refers to patient behavior that is inconsistent with prescribed therapy. Examples of noncompliance include not taking medication and not making lifestyle modifications as directed.

Studies show that half of all patients being treated for hypertension discontinue therapy during the first year.

Noncompliance causes an increase in hospital admissions and physician visits, at an annual cost of \$8.5 billion.

Most often, the cause for noncompliance can be attributed to misunderstanding, confusion, or miscommunication about hypertension and treatment.

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## **The Future of Geriatric Education** ***The Interdisciplinary Team***

*Peter P. Lamy, Ph.D., Sc. D.*

The requirements for education and training necessary to meet the needs of the nation's elderly are largely determined by the needs of an expanding elderly population. This segment of the U.S. population will have increased by 10 million between 1980 and 2000, with the largest increase among those 85 years of age and over. Indeed, the latter group is the fastest growing segment of the US population.

In rapid growth of the oldest age groups will have a major impact on future health care costs. Without major changes in the health of our older population, these health care costs will escalate enormously. Yet, success in one area of health care may well lead to worsening of another patient population. For example, declines in mortality from heart disease in the younger-old could lead to survival of a population at risk for developing Alzheimer's disease.

Chronic health conditions disproportionately affect minority and poor elderly, who are less likely to have insurance and are more apt to wait until symptoms of chronic diseases become acute. Frail elderly, moreover, present with multiple interrelated problems, some of which go undetected<sup>1</sup>.

Comprehensive assessment cuts across disease categories, addressing physical, cognitive, emotional, and social function<sup>2</sup>. Thus, the "increasing number of elderly persons and dynamic changes in the health field present complex challenges to educators concerned with preparation of health professionals<sup>3</sup> who must be able to meet these challenges.

Demands for hospital care, and various options of long-term care and community services will grow at an accelerated pace. These demands can be met effectively and economically only if better educated and trained personnel and additional knowledge on prevention and treatment become available.

Principles guiding educational efforts in care for the elderly must give attention to the preparation of almost all health and human service professionals through basic and graduate education. Competent and adequate faculty are required to guide clinical activities. Interdisciplinary, collaborative, and community-based approaches are essential.<sup>4</sup> A wide variety of health and social service personnel and their schools must be involved in these efforts.<sup>4</sup>

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### ***Demands for hospital care, long term care, and community services will grow at an accelerated pace***

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It is suggested that an interdisciplinary approach to geriatric care is central to our ability to manage the chronic diseases so prevalent in the older population. For example, management of a patient with a dementing illness, in particular Alzheimer's disease, is the most demanding task, since, far too often, little positive outcome can be expected. A host of patient, caregiver, social, and medical factors need to be considered, in addition to medication

related factors. These can be addressed only in an interdisciplinary manner, with each member of an interdisciplinary team drawing on the expertise of the other members.

### **Care of the Elderly A Conceptual Approach**

Good care of the elderly has been conceptualized<sup>5,6</sup> with respect to two dimensions that constitute quality of care, i.e., the interaction process between the patient and the providers. It is suggested that attitudes of health care providers and the method by which care is delivered are paramount to achieving these goals. In turn, it is suggested that the team approach is essential in providing care to the elderly.

Baker<sup>7</sup> makes the point that most health professionals, including physicians, prefer to treat an elderly patient with a well-diagnosed disease rather than an elderly patient with well-diagnosed functional (and, presumably, cognitive) disabilities. Indeed, professionals' attitudes toward the elderly may be more negative among those working with the elderly than in those not working with them<sup>8</sup>. There is a general lack of understanding of factors which would explain why some health care professionals are favorably inclined to the elderly, while others are not. Positive attitudes toward the elderly can largely be shaped within the context of a geriatric team.

Furthermore, introduction of concepts of normal aging, related to biological, psychological, and social changes that occur with aging into the

clinical education and training of health care providers will greatly facilitate communications, sensitivity, and understanding between practitioners and their patients.

There is a need for all health professionals to acquire special geriatric knowledge and interdisciplinary team skills to address the acute and chronic medical and social conditions which prevail among the elderly. The necessary understanding by each team member of the other disciplines' approaches to solutions cannot be achieved without a basic knowledge of each profession's approach to patient care.

Yet, the notion of teamwork is still poorly defined and understood, and the supposed benefits for patients are not always readily apparent. It is not unlikely that interdisciplinary decision-making and work with patients/families can, under some circumstances, take on the appearance of collaboration among a team of expert colleagues, which co-opts the patient/caregiver to the status of team members.

But, very often, interdisciplinary work with patients is coordinated not by mutual collaboration among a team of equals, but by means of established work routines which are broadly applied to whole categories of patients, and by the operation of the established and traditional hierarchy of health care.

Thus, what is needed is a patient-centered team approach to geriatric care. But even then, the problem of consensus between health care professionals on one hand and patient/caregiver on the other may arise. A mini consensus is certainly a necessity, since the traditional concepts of healing and recovery are now viewed only as part of a larger, more global task, i.e. recovery, rehabilitation (to the extent possible) and subsequent maintenance of health. Importantly, it must be understood that the goals of acute and long-term care differ sharply. "Cure" is no longer a goal in many instances of long-term care, but maintenance of a patient's functional status and quality of life assumes priority.

The team approach is especially important when elderly with chronic diseases are transferred from one sector of the continuum of care to another. They are often readmitted to the higher care sector within a short period of time for the same condition or problem. Thus, assessment of readiness for discharge has become an economic issue (readmission is a costly process) and a quality-of-care issue<sup>10</sup>. Seventeen percent of general medicine patients may experience non-elective readmission within 90 days of discharge<sup>11</sup>, 22% of patients medicare beneficiaries may be readmitted within 60 days<sup>12</sup>, 27% of patients over age 70 may be readmitted within six weeks<sup>13</sup>, and 36% of patients 65 and over with CHF will be readmitted within six months.<sup>14</sup>

#### A New Educational Experience

Clinical training sites will be needed that are anchored in ambulatory care facilities radiating out to other parts of the health care



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system such as the acute care hospital, the nursing home, home and residential care. This recognizes the need for cultural and institutional change, so that neither the acute care hospital nor the nursing home would continue to be considered the only focus of geriatric long-term care. The mode of decision-making in this model is interactive and collaborative, with the patient/caregiver holding significant decision-making power. The model, thus, is patient/caregiver centered.

The educational system proposed is an interlocking one that offers training for various health care professionals. It views each professional's skills in relation to total services and takes into account the continuum of care in the conduct of education and training. Indeed, a transformed system points to the need for major changes in the education of all health care professionals. Given the importance of collaborative decision-making, the education of health care professionals must take place in close proximity of joint teaching and learning experiences. Sharing at the educational level will facilitate later sharing in the work environment. There is an urgent need to identify the effectiveness of an interdisciplinary (interprofessional) health care team in the continuum of care, a continuum that includes preventative as well as treatment services, chronic care as well as acute and long-term care, and outpatient as well as inpatient services. Because the Federal government is concerned with maintaining and improving access along the continuum of health services, it is most important that the several parts of the continuum understand the role of each part, the options and opportunities that each part offers, and the role of the health care team in each part. This would seem highly desirable so that scarce personnel resources are utilized only for tasks that require their level of training and skill. This would also allow an effective team approach, organizing health care personnel into teams responsible for access to a

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### *Goals of Successful Geriatric Therapy*

To preserve maximum independence of the affected individual (by addressing mental and functional problems).

To provide access to a continuum of care.

To efficiently coordinate the provision of care to maximize the match between available services and the needs and preferences of the individual and the family.

To preserve the dignity of the affected individual.

To reduce the severity of symptoms.

To treat medical problems that may worsen dementia or cause pain and suffering.

To cultivate preserved abilities and reduce the adverse effects of lost abilities.

To foster the integrity of the family and minimize family stress.

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continuum of care for individual patients, thus recognizing and optimizing individual levels of competence and knowledge. Among curricula topics should be current epidemiological, social, attitudinal, and program trends in aging and health; aging in the future, expectations and the economic feasibility of health systems for the elderly, legal considerations, and, importantly, ethics.

A nation's health policy is its strategy for controlling and optimizing the social uses of its medical knowledge and resources. Human values guide and justify the choice of these goals, priorities, and means that make up this strategy. Ethics acts as the bridge between health policy and values. Widespread interest in the ethical issues associated with medicine, health care and bioscience arose in the latter half of the 1960s. The problem of selecting patients for chronic hemodialysis was the first issue to arouse public and scholarly discussion.

Two Federal commissions were established during those years, The National Commission for the

Protection of Human Subjects of Biomedical and Behavioral Research (1979-1983) and The President's Commission for the Study of The Ethical Problems in Medicine and in Behavioral and biomedical Research (1979-1983). Since then, the interest in the behavior of health care professionals and their relationship with the patient and caregiver has increased, as scientific progress has given new knowledge to medical science and new technology to address chronic diseases in particular.

Within that context has come the recognition that minorities in general, and African-Americans in particular have had a historical, socioeconomic, and cultural experience that gives them a different moral and ethical perspective from the majority of health care providers who are still largely of Euro-American background.

Thus, ethical dilemmas have been emerging, and are likely to continue to emerge, in particular with patients with dementing illnesses and their families. Decisions that are within a patient's rights are still made by health care providers often exerting a

strong paternalism and not responding to patient/family appeals. Issues such as the "living will" or "durable power of attorney", of the use of life-sustaining technology, of active or passive euthanasia will increasingly need to be addressed, if a harmonious relationship between the health care team and the patient/family is to be achieved. The ethical values of the health care provider will partly be determined by the education received, and it is most important that a major part of that educational process be part of the clinical team experience.

### Goals of the Proposed Clinical Training Sites

Certain chronic health conditions disproportionately affect minority and poor persons, who are less likely to have health insurance and more apt to wait until symptoms of chronic diseases become acute. These must be addressed. The major goal of the proposed clinical educational sites will be to teach a variety of health professionals the benefits to themselves and the patient/family of a cooperative approach to chronic disease management.

Specifically, the goals of successful geriatric therapy listed in the table on the previous page must be addressed.

It is suggested that attainment of all goals will not always be possible. However, attainment even of some goals will not be possible unless well-educated health professionals work as a team.

It is suggested that, once the sub-goals have been addressed, the outcome will be as follows: 1) an advanced level of health care will be provided. Future health care providers will have learned the provision of and outcome of this advanced level of care; 2) each discipline will perform health care services in an interdisciplinary and cross-discipline fashion. ■

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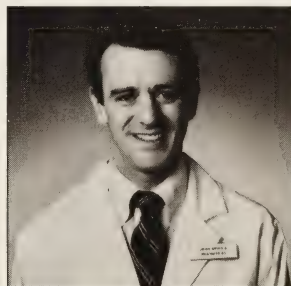
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## Investing For Today *The Risk of Taking No Risk*

Daniel K. Hays

The squeeze on investment income continues, as the latest round of credit easing by the Federal Reserve pushed the gap between short-term and long-term interest rates to one of the widest spreads ever.

By year-end, many analysts believe short-term rates could decline even further, and long-term bond yields may move lower as well.

The graph accompanying this article dramatically shows how far short-term yields have fallen since 1989. Two years ago, yields on three-month treasury bills at 7.9% were essentially the same as those for 30-year treasury bonds, whereas today, short-term bills yield only about 5%, while rates on long-term bonds are nearly 8%.

### Significance for fixed-income investors

If you rely on short-term savings and money market accounts as safe, dependable investments, you have seen the income from those investments, you have seen the income from those investments decline significantly. With savings currently paying about 5% yearly, and the inflation rate nearly that much as well, you probably won't even break even after taxes. As interest rates drift further lower, it will be even more difficult to reinvest principal and at profitable rates.

If you're already invested in longer-term instruments that mature within the next few years and you won't need the proceeds immediately, you should consider maintaining these extended maturities while attractive rates are still available. By extending maturities, the potential for enhancing return and increasing annual income is greater.

### Significance for equity investors

There are many analysts who believe equity markets remain attractive due to the decline in short-term interest rates that precipitated a shift in assets from CD's to stocks. Moreover, the slow pace of the economic recovery, the prospects for continued low inflation, and the focus on domestic issues as we head into an election year are other factors that bode well for the stock market.

Typically, the stock market has moved higher at the conclusion of a recession. The accompanying table shows

the eight recessionary periods between 1949 and 1982 and the percentage change in the Dow Jones Industrial Average that occurred during each. As you can see, stocks performed well in all periods and the average change was +23.4%.

While the table focuses on the stocks of large companies, many analysts think the current environment favors attractive growth opportunities in stocks of small companies. In fact, some traders estimate that small stocks have the potential to increase earnings at 15% per year or more over the next five years.

Which growth opportunities you select depends on the risk you're willing to take. Generally, small company stocks are more volatile than those of larger companies and, therefore, have more risk, but offer the potential for higher returns.

### *Stocks Do Well in Years That Recessions End*

Recession End	Begin	Industrial Average End	% Change
1949	177.30	200.13	12.9%
1954	280.90	404.39	44.0
1958	435.69	583.65	34.0
1961	615.89	731.14	18.7
1970	800.36	838.92	4.8
1975	616.24	852.41	38.3
1980	838.74	963.99	14.9
1982	<u>875.00</u>	<u>1046.54</u>	<u>19.6</u>

Average 23.4%

Current 2950.00 ? ?

Recession periods designated by the National Bureau of Economic Research

### Taking prudent risk

Perhaps now is the time to seize the day! Earning a higher return requires taking some prudent risk. This means investing where there is opportunity to enhance total return (principal value plus interest or dividends) at the least risk to your principal and still keep ahead of inflation.

Above all, it's important to devise a strategy based on your own comfort with risk. The challenge goes beyond selecting specific instruments. It is how you deploy your dollars among stocks, bonds and cash that determines your overall return.

### A typical allocation

A recommended allocation for a typical conservative investor in today's environment is 5% cash, 35% in fixed-income securities and 60% in equities.

Stock selection should focus on investment-grade companies with the capability to post significant earnings

growth over the next economic cycle. Examples would include firms involved in energy, health care and communication services.

Within the fixed income portion of a portfolio, bonds with maturities of 5 to 15 years look particularly attractive. Of course, the recommended mix for you specific circumstances may be different. Your investment consultant can help you determine the allocation that best suits your needs.

If the thought of risk is unsettling, just remember that the cost of living will be much greater in the years ahead. Also, note that a small difference in returns today can make a big difference in what you have for the future. With prudent risk, you can enhance your opportunity for better returns.

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Daniel K. Hays is a fellow MPhA member and investment consultant in Lutherville, Maryland. If you have any questions, he can be reached at 321-6900.

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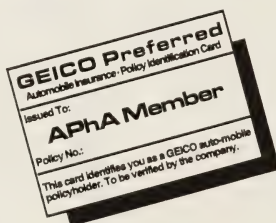
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## Preparing For An Inspection

Melvin N. Rubin, P.D.

You just opened the pharmacy, fairly bright-eyed and still a little bushy-tailed, ready to take on the world -- or at least solve your patients' problems and help improve their health and quality of life.

You're all psyched up and ready to go.

The first person you see flashes a badge. "Doesn't look like a policeman," you think. "Does the IRS have badges?" No, it's only your friendly Division of Drug Control inspector ready to do your annual inspection.

You heave a sigh of relief. After all, you know you don't divert drugs, don't have your pharmacy name on any of the physician prescription blanks, and you even fill out the syringe and paraphernalia book. But wait a minute! There's a lot of material you have to show your friendly pharmacy inspector which you don't even remember *seeing* since his last visit.

So much for patient contact. Now your time will be taken up by a scavenger hunt. "Mary, you find the license. Joe, you find the CDS inventory". No time for patients now -- *scramble*.

There is a better way to cope with the annual unannounced inspection. Maryland pharmacies are fortunate that all of our inspectors are pharmacists and understand our problems; however, this won't stop them from carrying out their mission of protecting the public by assuring that pharmacy is practiced within the limits of the law. If you are perpetually ready for inspection everyone gains -- you, your staff, and especially the patient who needs help that day.

Being ready can be broken down into two parts. First, make sure that all required routine bookkeeping is kept up-to-date. Red C's, separate Schedule II filing, etc. should be done on an "as-you-go" or daily basis. But what about all the records that need inspection? Can you find them quickly, or better yet, can the inspector do his job without imposing too much on your time? Since the latter seems preferable, MPhA is providing you with a chart to complete. Completed and updated as files are moved may help get you through an inspection with a smile. There'll even be time to tell Mrs Smith that the decongestant for little Cindy's ears works better by mouth than used to bathe her ear. ■

*MPhA Pharmacy Inspection Form*

<i>Record Required</i>	<i>Location</i>
Current Maryland CDS Registration	
Current Federal DEA Registration	
Current Maryland Drug Formulary	
Current Schedule II Files	
Biannual CDS Inventory	
Schedule II Invoices	
Schedule III, IV, and V Invoices	
Old Prescription Files (maintain for five years)	
Pharmacists State Board Certificate	
Current Maryland Pharmacy Permit	
Paraphernalia Register	
Schedule II Drug Location	
Reference Material ( <i>USP, Facts</i> , etc.)	
Third Copy DEA Order Form 222	

Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by October 31, 1992. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name \_\_\_\_\_

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Is this program used to meet your mandatory CE requirements?      ☐ Yes      ☐ No

Was this issue/article useful to your in your practice?      ☐ Yes      ☐ No

**The questions for this month's continuing education quiz are drawn from  
the articles on Hypertension throughout the April 1992 journal.**

1. Which of the following disease states is not an indication for a calcium channel blocker?
  - a. hypertension
  - b. congestive heart failure
  - c. angina
  - d. arrhythmias
2. Which of the following calcium channel blockers has a lower incidence of side effects on the heart or peripheral vasculature?
  - a. diltiazem
  - b. nifedipine
  - c. verapamil
  - d. bepridil
3. Which immediate release product is not indicated for hypertension?
  - a. verapamil
  - b. diltiazem
  - c. felodipine
  - d. nifedipine
4. What is the role of Angiotensin I in the RAS system?
  - a. converts to angiotensin II by the angiotensin converting enzyme
  - b. degrades bradykinin, a vasodilator
  - c. it acts as a potent vasoconstrictor
  - d. acts directly on renal sodium reabsorption
5. Which ACE inhibitor is not considered a pro-drug?
  - a. enalapril
  - b. lisinopril
  - c. captopril
6. Which of the following is not appropriate pain therapy for a medication controlled hypertensive?
  - a. ibuprofen in small doses with frequent monitoring
  - b. a renal sparing NSAID with careful monitoring
  - c. naproxen 500 mg in twice daily doses
  - d. acetaminophen if anti-inflammatory effects are not needed
7. Restoration of renal blood flow (RBF) is largely caused by:
  - a. increase in coronary blood flow
  - b. renal microvasculature constriction
  - c. renin-angiotensin-aldosterone system
  - d. activation of metabolic enzymes in the kidney
8. Which of the following is not a reason for noncompliance for hypertensive patients?
  - a. cost of medications and lab tests
  - b. the effects of the medications on lifestyle
  - c. misunderstanding about the disease or drugs
  - d. involvement of the patient in their treatment and disease control regimen
9. There are many barriers in treating the elderly. Which of the following is not a barrier?
  - a. cultural differences
  - b. ethical differences
  - c. open communication
  - d. financial problems

# Classified

"Rx" LICENSE PLATES are still available through MPhA. When you receive your license renewal form, contact Mary Ann at (410) 727-0746 for details. The plates say "Pharmacist Association" in addition to "RX" and the number. This offer is open only to members and their immediate family.

**THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION**, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (410) 358-7036.

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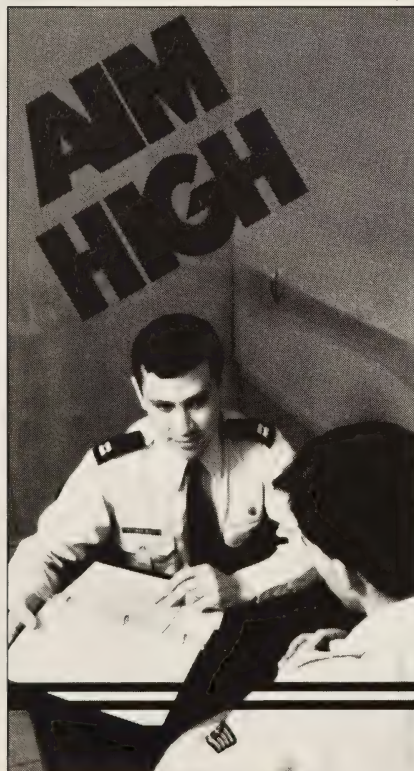
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- ◆ Tracking & Resolving Denials
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- ◆ Computer Options When & What

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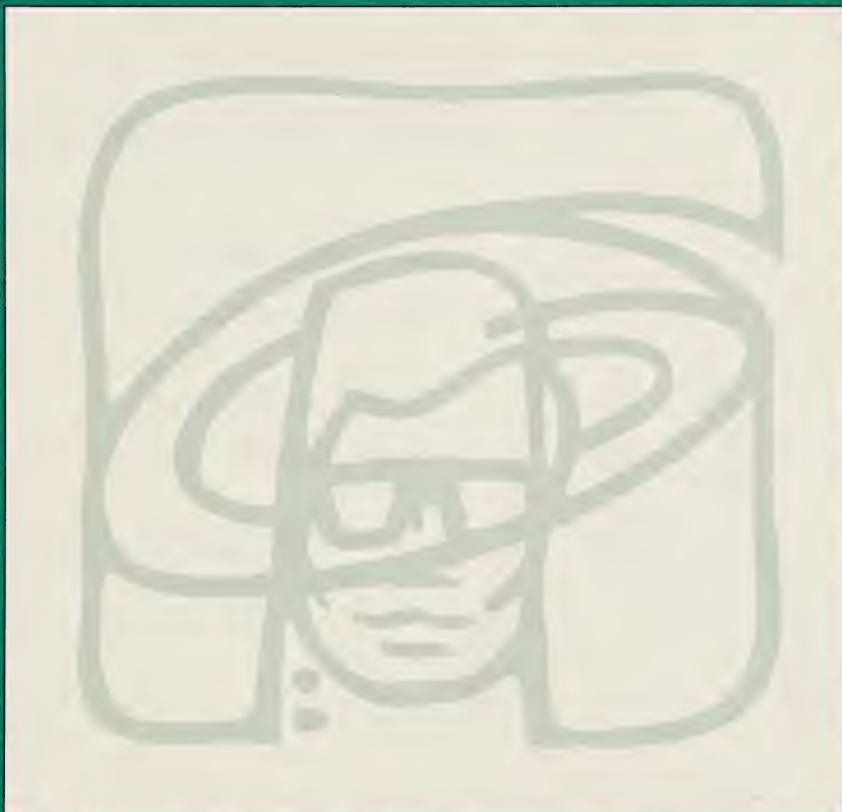
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# The Maryland Pharmacist

VOL. 68

May, 1992

No. 5



**Impaired Professionals**  
*Helping pharmacists find the road to recovery*

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## Pharmacist Rehabilitation Committee

### *A Report on Nine Years of Service*

*Harry B. Finke, B.S. Pharm.*



*Harry B. Finke*

In the summer of 1983, former MPhA Executive Director Dave Banta made a phone call suggesting that a committee be formed to direct the treatment and rehabilitation of chemically dependent pharmacists. As a result, a group of pharmacists convened at the School of Pharmacy with Maryland State Board of Pharmacy members and a physician. After two months of defining our role, the State Board of Pharmacy's function and formulating our by-laws, the Maryland Pharmacists' Rehabilitation Committee was created (former name Maryland Impaired Pharmacists' Committee). The most rewarding and beneficial relationship that evolved from the beginning was the open and honest commitment of the Maryland State Board of Pharmacy to co-operate with our Committee in an ad-hoc capacity. We have enjoyed this relationship for nine years in a cooperative effort to help chemically dependent pharmacists into recovery.

Over the years we have developed a very comprehensive and equitable contract. Legislation has been passed to make our records non-discoverable and we have built many bridges to various treatment centers around the state. The success of our program is based on commitment by members, understanding the disease of addiction, the dilemma of the chemically impaired pharmacist, and confidentiality. Without strict confidentiality the entire program would be a failure. We pride ourselves on the success we have had over the last nine years.

The future of our committee is bright. We have enabled many pharmacists to return to a viable practice of pharmacy. We look forward to the cooperation of many of the employers around the state of Maryland who have given recovering pharmacists a chance to regain employment and self esteem. We know that more chemically dependent pharmacists are seeking help, going through treatment programs successfully, staying in recovery and returning to the practice of pharmacy as well respected health care practitioners.

We realize that education is the cornerstone of our continuing success in the pharmacy community so we will be conducting future Continuing Education programs throughout the state. We would like to see more pharmacists get involved, take a stand of treatment in lieu of terminating a chemically impaired pharmacist. When the pharmacist is terminated it allows them to continue to function in the work place which jeopardizes the pharmacist, the employer and the safety of the public. There are still many bridges to be built with independent employers, HMO's and Chain Drug Store Management. We on the Committee see this as a challenge that we can meet through cooperation and education among all aspects of pharmacy.

Once a pharmacist has signed a contract there are many treatment options available so each recovering pharmacist has their own tailored treatment place. The treatment could range from outpatient by going to group therapy and support meeting (Alcoholic's Anonymous, Narcotics Anonymous, Cocaine Anonymous), and R.E.T. (Rational Emotive Therapy). One the program is completed by the pharmacist all records are destroyed except statistical data. We are proud to say as a peer committee we have greater

than a 90% success rate, however it is not us that deserve the accolades, but the recovering pharmacists who trusted our guidance and support and had enough stamina, humility and insight to make a beneficial change in their behavior which allowed them to regain their self-esteem, careers and family support. All of us on the Committee applaud you and wish you many successes in your pharmacy careers.

Re-employment is very difficult for the recovering pharmacist because of guilt, embarrassment, low self-esteem and insecurity. We urge all recovering pharmacists to be truthful and honest in their interviews. It would be incorrect to say that anytime you hire a pharmacist you are not taking a risk. There is no such thing as a risk free employee. The question is, How does a recovering pharmacist compare with an unknown history of a pharmacist? At least with the recovering pharmacist you know where you stand, whereas the employer can never be sure about the pharmacist from the general employment pool. Chemical Dependency on a national basis for pharmacists has an incidence rate of 16 to 26%. There is always a risk in life. For the supervisor, their performance is based on their ability to hire a competent pharmacist. This is not risk free, but with a recovering pharmacist you know for sure that the pharmacist you hire is who they say they are. The recovering pharmacist may have to be on a flexible work schedule initially because of the Aftercare Program so we ask for cooperation with the employer. Remember, we are a helping profession. We would not refuse to hire a person with diabetes or hypertension because of their disease. We look forward to continue working with the pharmacy community to help guide, manage and direct the treatment of our fellow professionals. ■

### ***Intervention***

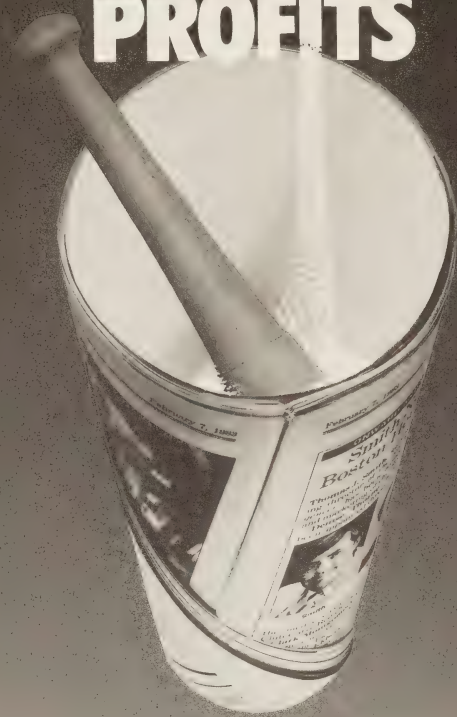
#### ***How it Works for the Chemically Dependent Pharmacist***

If you are driving down the road in your car and you become aware of some erratic behavior in your car you begin to formulate a plan to rectify the problem. The first step is to take the car to a mechanic for a diagnostic workup. One of two possibilities exist: a minor problem can be repaired immediately by the mechanic or the car may require a major over haul which would require you to leave the car with the mechanic. In either situation you had an initial suspicion that something was wrong because of your car's inappropriate behavior so you sought help be a qualified person.

The chemically impaired pharmacist is like the car. Someone, a co-worker, friend or significant other recognizes a negative change in the pharmacist's behavior. The friend or co-worker would like to have the pharmacist evaluated but is not sure how to proceed.

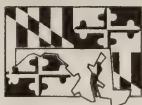
By contacting the Maryland Pharmacists' Rehabilitation Committee, the pharmacist can be evaluated: if it is not a chemical dependency problem then the pharmacist can continue working in his/her respective practice. If there is a chemical dependency problem then an intervention is needed to prevent, change and cease the negative behavior caused by the chemical dependency. This involves gathering information and having a meeting with the pharmacist. Once it is determined that the pharmacist has a definite problem a treatment plan is formulated and put into effect. The pharmacist spends some time in the "garage" getting "repaired" so he/she can resume a successful career in pharmacy without chemical impairment. Remember a chemically dependent pharmacist does not have to bottom out and los everything before they can receive guidance and help. It is clinically documented that the earlier the intervention is performed on a chemically dependent individual the greater their chances are for early recovery.

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## What is Addiction?

*Donald Ottenburg, M.D.*

First of all, addiction is a way of life.

It's a way of smoothing out difficulty. It's a way of soothing pain. It's not only a means of escape, it's also a means of living. The escape may be from tension, fear, anger, inadequacy. It's a means of feeling normal and acceptable, even if only temporarily. It's a false mechanism of fulfillment.

It's a means of achieving in fantasy that which cannot be attained in reality. It's a means of being what you want to be. Braver, smarter, more competent, more likable, more acceptable, taller, thinner, without pimples, uncrippled. It's a means of adjustment to reality which may be frightening or over powering, unyielding, threatening, or destroying.

It's a coping mechanism in a world that's too difficult or too alien. It's a bridge to other people. A way of breaking out of unendurable isolation. It's a way of achieving human contact.

Addiction expresses anger and represses anger. One can live with rage a long time under the influence of drugs.

Addiction may be the most effective weapon of retaliation. A young person may resist letting go of the addiction. They resist becoming well, because it is the best, perhaps the only way, to fight and hurt parents. We've seen the same reaction in the alcoholic's case.

One can live with almost any disability, disappointment, anguish or pain when addicted. This is, after all, close to the use that's made of narcotics in the practice of medicine. Addiction provides compensation for unbearable inadequacy. Sometimes for psychosis. It is a means of achieving sexual identity, and, at times, performance.

Addiction rescues from the abyss of loneliness. It's counterfeit joy. It's also counterfeit courage, beauty, friendship, love, meaning. It's a surrender. It's an attachment to a master. But, it's also a means of relating to life one cannot find or experience otherwise. Addiction may provide the only reason for getting out of bed in the morning and the only place to go after arising. Addiction is a club that's open twenty-four hours a day, seven days a week; dues payable on the installment plan.

Addiction is a taste, an itch, a tingle in the back of the throat. Addiction is a taste that starts in the mouth and spreads to every cell of the body.

Addiction is living just a stroke away from orgasm. Can you wait? Can you stop? Can you not go ahead?

Addiction is an aroma that invades every room in the house, touches every article of clothing, every piece of furniture - the sickening sweet smell of jasmine seeping through the walls. It's also the faint musty odor of smoke that pervade the promises and everything in them and doesn't evaporate for months or years after the fire is out.

A fresh addiction is an affair with a new lover - inviting, exciting, delighting. It's always the rush of feeling, always the response, always the orgasm. A fresh addiction is a lover always waiting, always ready. Addiction is the tormenting thrill of your name whispered, moaned, over and over.

An old addiction is like a burnt out marriage where motions are gone through, out of habit and need. An old addiction is a dry, joyless orgasm. An old addiction is paying last year's dues. Paying the tab for a good time that is over and can hardly be remembered.

An old addiction is a handful of tokens for the subway when it used to cost seven cents.

An old addiction is paying blackmail in a protection racket. Every day the hood comes round and every day you pay off just to avoid pain and agony.

Addiction is embezzlement of life rather than money. The same deepening hold, the same need to cover tracks, the same impossibility of stopping, the same, even worse, odds of getting caught.

Addiction, in the young, is an alternative to the struggle against adolescent self-doubt, fear and confusion. Addiction is a way of consolidating life's doubts. It takes all the separate pains, conflicts, and inadequacies and converts them into a single anguish - a single purpose and struggle. With all its denial of life and threatening of life and risking of life, addiction is still and above all, a means of survival. It's a life.

A man named Isadore Chein, the senior author of the book, *The Road to H*, who speaks very wisely about addiction says simply, "Heroin addiction serves three purposes in the addict: First, it gives the addict individual identity. He's no longer nobody. He's an addict. Next, it gives him group identity, since any addict is automatically a part of a very strong fraternity. He's a member of the club. There are many others like him and he has a great deal that he shares with a whole subculture."

Finally, addiction is a vocation and this is simply a reflection of the fact that it's a full-time job to be an addict or an alcoholic. ■

## I Am a Pharmacist and a Drug Addict

*Anonymous*

I am a pharmacist. I am also a drug addict.

For years, I did not want to believe that I had a problem I could not control. I was using Valium only because I could not sleep and Tylox and Demerol only to ease the pain of my arthritis. Or so I told myself.

I convinced myself that I needed these drugs only for medicinal reasons. I denied that I was addicted to these drugs. I knew that I could stop using these pills anytime I wanted to. My denial was powerful and successful.

The day came, however, when I ran out of pills and began to go into severe withdrawal. As I grew sicker and sicker, I knew that I had reached the end of my charade. That's when I finally realized that my problem had escalated out of control. I then took my first step toward recovery -- I admitted my addiction to my wife and my father, and that I was powerless to help myself.

Next, I called my family internist, told him of my problem, and asked him to admit me to detoxification center of the local hospital.

I was terrified that I would be found out. I was a well-respected pharmacist in the community where I had grown up. I had a beautiful wife, two wonderful children, and a big new house in a prosperous neighborhood. My material trappings had allowed me to mask my problem well. If I were successful enough to have acquired this lifestyle, then I could not possibly be a drug addict.

Unknown to me, my employer had reported my problem to the local police task force on drug abuse. On the way to detox, the task force officers stopped me, arrested me, and took me to jail. Because of the quantity of drugs I was consuming, I was charged with two counts of possession with intent to distribute, and nine counts of possession of a controlled dangerous substance.

I could never have imagined the humiliation, pain and fear that followed. I was on the front page of the newspaper and the lead story on the evening news. I was brought into court in handcuffs and shackles. At least 20 narcotics officers combed every inch of my house in search of a drug kungbin.

Instead they found a broken and addicted pharmacist. I have lost my pharmacy license, the respect of my peers, my entire financial savings, and my promising career. I have been humiliated and humbled.

Denial is the reason that I had to hit rock bottom before I could face my problem. If I could have looked honestly at myself, and what I was doing to myself, I

might have been able to get help sooner. I also believe that I might have sought help earlier if I had not been a pharmacist. I feared the consequences if I came clean. Would my employer have to know? Would I lose my pharmacy license? Would the DEA become involved? Would I be arrested?

---

*I had to hit rock bottom before  
I could face up to my addiction*

---

In the face of these questions, I convinced myself that I could simply stop using these drugs on my own. It was like going on a "diet" -- I could always start the next day.

I started using pot in high school and experimented with numerous drugs over the years. If drugs were not readily available, I turned to alcohol. I fell little by little, deeper and deeper, into the pits of hell. If drug addiction happened overnight, it would be easy to spot. Instead, the addiction disease manifests itself gradually over time.

I could not believe that I was going to jail. I had thought that I would be released on my own recognizance. But when I went before the hearing officer, and he told me that I faced 100 years worth of charges and my bail had been set at \$100,000, I felt fear that I had never known before.

The next day, my bond was decreased to \$25,000 and I was sent to detox. After seven sleepless nights, and, fortunately no seizures, I was sent to rehabilitation. I spent the next 30 days learning to face my problems head on rather than using drugs to forget about them.

Financially and materialistically, this past year has been the worst year of my life. I have lost almost everything but my family. There are no more second chances for me.

But I am rebuilding my life -- emotionally, physically, and spiritually. I have learned to enjoy the simple things in life rather than the material trappings. I have learned to life in the present and not to worry so much about what problems the future might bring.

And, I have learned that I cannot put any addicting drugs into my body. There are no exceptions.

Coming clean, with all of its pain, is better than dying. Addiction leads to death, and I'm not ready to die. ■

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## Using the Pharmacists Rehabilitation Committee

*Penney Miller, P.D.*

The intent of this article is to clarify the role of the Pharmacists' Rehabilitation Committee (PRC), explain how to contact the Committee, and to give insight into the chain of events that follows contact.

### **PRC and Board of Pharmacy Roles**

Many people are confused about the roles of the PRC and the Board of Pharmacy. Some may think the PRC is a subcommittee of the Board. The Board of Pharmacy and the PRC are two separate bodies with different priorities. The Board of Pharmacy is a licensing and regulatory body. The PRC is an advocacy group not affiliated with any government agency. Both share the common interest of seeing affected pharmacists receive treatment for chemical dependence.

The PRC receives cases through self-referral, referral by an employer, colleague, friend or family member, and at times, referral from the State Board. The confidentiality of the PRC records is protected by state law. These records are "undiscoverable" as evidence in legal proceedings against pharmacists.

Recovering pharmacists participating in the PRC program sign a contract binding them to certain recovery activities in return for the Committee's advocacy on their behalf. The most important part of the contract indicates that failure to comply with the contract may result in the referral of the case to the State Board with all of the documentation in the Committee's possession. This is the only way in which the State Board would learn from the PRC that a self- or other-referred pharmacist is experiencing problems and has been involved in treatment.

The State Board handles infractions of the Pharmacy Practice Act, the state law outlining the basic minimum requirements of pharmacy practice. At times the Board must deal with pharmacists who allegedly violate the Act and who are also potential candidates for chemical dependency treatment. These individuals, charged with and perhaps found guilty of violations of the law, are Board-referred to the PRC under an order of the Board. A frequent condition of this order is pharmacist participation in the PRC program of diagnosis and treatment. Accompanying this is a reporting obligation placed upon the PRC, the individual pharmacist, and the treatment center managing the case.

### **Contacting the Committee**

Anyone with a legitimate concern about a pharmacist who may be chemically impaired may contact the Committee, whether they be the pharmacist's spouse, employer, customer, co-worker, or others.

The Committee consists of volunteer health professionals, primarily pharmacists who are interested in assisting chemically impaired pharmacists. The Committee may be reached by phoning the Maryland Pharmacists' Association (410) 727-0746. The MPhA office will refer the caller to a Committee officer who will discuss the situation and get as many facts as possible. Confidentiality will be strictly maintained and the identity of the caller may remain anonymous to the impaired pharmacist.

Regardless of the source, the Committee must be satisfied that the information is bona fide and serious enough to warrant an evaluation of the pharmacist. When all information is verified and substantiated, the Committee will contact the pharmacist suspected of impairment by registered mail to set up an interview and possible intervention.

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### ***Before taking any action, the Pharmacists Rehabilitation Committee must verify and substantiate all evidence***

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At least two Committee members will be present at the interview. If they find sufficient evidence that the pharmacist is suffering from chemical dependence significant enough to impair professional performance, the pharmacist will be advised to undergo treatment.

Treatment will consist of detoxification, complete physician and psychiatric evaluation and other modalities of care known to be appropriate for the individual referred. The impaired pharmacist must choose a treating physician suitable to the Committee. They must also enter into a signed contract between themselves and the Committee to continue in the prescribed treatment program for at least two years.

During the contract period, one Committee member becomes the recovering pharmacist's contact person. The

recovering pharmacist is required to discuss their progress with the contact person weekly. This relationship is very important to the recovering pharmacist as it enables them to stay in touch with their professional colleagues and establishes a basis on which the Committee can advocate the pharmacist's return to practice at the appropriate time.

If the pharmacist resists treatment, a second meeting with the Committee will be arranged. If the pharmacist's resistance continues they will be advised that their name will be given to the State Board Review Committee, although no information other than the nature of their problem and refusal to accept treatment will be conveyed.

The Committee, working with the treating physician, will determine when a pharmacist may return to practice. If a pharmacist drops out of treatment prematurely, the Committee will try to persuade them to resume therapy. If the pharmacist fails to do so, the Committee will threaten to notify the State Board of Pharmacy.

A pharmacist who relapses or violates their contract with the Committee may be requested to extend their commitment to treatment for more than the original two years. When all contract requirements are met by the pharmacist, all Committee records pertaining to the case are destroyed.

### Taking the First Step

Many people are afraid to contact the Committee; the reasons are numerous. Spouses, after living with an impaired pharmacist for many years may unconsciously facilitate the dependence behavior. They may themselves seek this lifestyle because of childhood influences, feel they would be betraying their spouse by seeking help, or may even fear the financial consequences of an interruption in income while the pharmacist receives treatment.

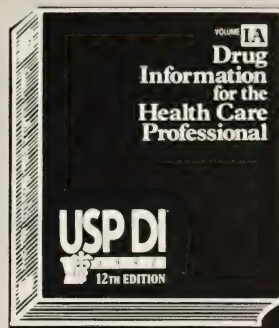
Co-workers may feel reluctant to become personally involved with an impaired pharmacist's problems. "It's not my place to make that kind of call" is a common excuse.

Employers intentionally avoid confronting the suspected impaired pharmacist on only unsubstantiated or secondhand information; yet they have a responsibility to act in a professionally prudent manner to ensure the safety of the public under their pharmacy's care.

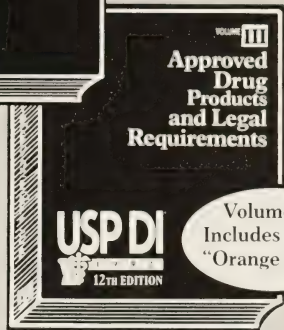
The impaired pharmacist may deny their problem, or fear the stigmas attached to treatment and affiliation with the Rehabilitation Committee.

Whatever your role or reason, the Committee urges you to act. The prognosis of a chemically impaired person worsens day by day. Their behavior affects everyone around them -- their family, their colleagues, and their patients. By contacting the Committee instead of hiding or ignoring the problem, the consequences suffered are likely to be less severe for all concerned. ■

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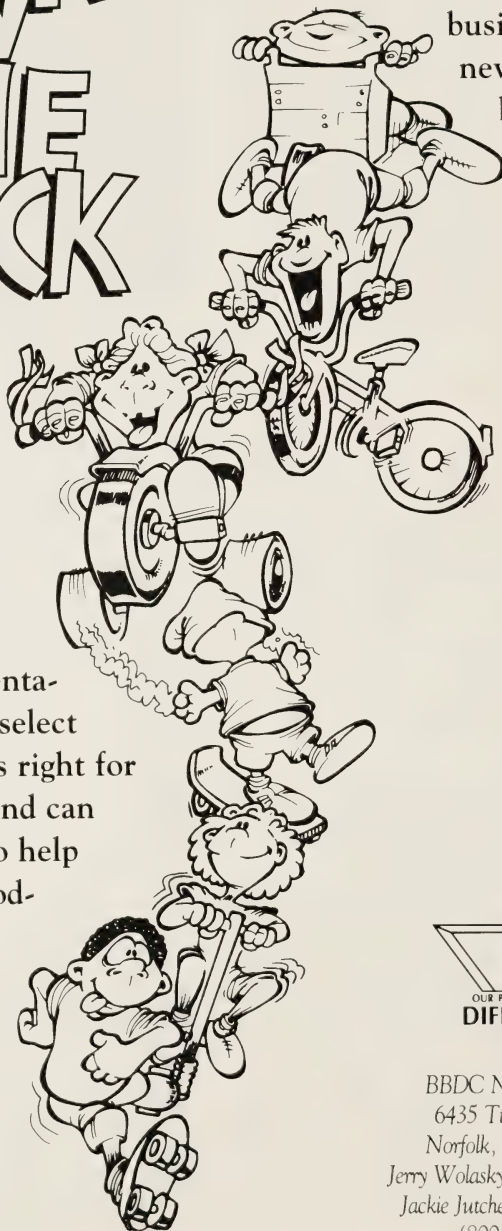
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## Working with the Board of Pharmacy

### *Everything You Always Wanted to Know About the State Board But Were Afraid to Ask!*

*Roslyn Scheer, M.A.S., Executive Director, Maryland State Board of Pharmacy*



*Roslyn Scheer*

As a result of increasing experience with substance abuse, the Maryland Board of Pharmacy has developed an effective procedure for interacting with impaired pharmacists. The Board's actions are predictable. They follow a logical sequence that is effective and beneficial, though not necessarily comfortable for the participating pharmacist.

#### **Voluntary Rehabilitation**

If someone calls the Board office concerning an impaired friend or family member, it is recommended that the caller contact the Pharmacists Rehabilitation Committee of MPhA, MSHP and the University of Maryland School of Pharmacy. Voluntary contact with the Committee before a legal problem develops provides a

mechanism to help the pharmacist privately without the Board having knowledge of the situation and, therefore, without disciplinary action against the pharmacist's license. The earlier someone begins the recovery process, the better it is for everyone.

If a store owner or manager cannot account for a quantity of controlled substances or has experienced a loss or theft of controlled substances, State laws and Federal regulations require that the Drug Enforcement Agency (DEA) and the Division of Drug Control be notified. Even if authorities must be notified, it is best to also contact the Rehabilitation Committee if there is an individual who needs help.

#### **Emergency Suspension**

If an individual is using drugs and working as a pharmacist, that individual runs the risk of having his or her pharmacist's license summarily suspended on an emergency basis without a hearing. However, a hearing will be held within 30 days of the Board receiving a written request from the pharmacist.

For the Board to issue an emergency suspension, the evidence must be substantial. Each year, however, several licenses are summarily suspended. The Board cannot allow known substance abusers to be dispensing while they are abusing drugs. Emergency cases receive high priority and are moved ahead of those that appear not to

place the public in jeopardy.

In the last thirteen years, not one of the Board's emergency suspensions has been challenged. Most of the individuals involved began recovery once their licenses were taken from them. This obviously is not the way anyone would recommend recovery begin. Once a license is suspended, however, the choices appear to be recovery or continued drug use. Fortunately, most pharmacists choose recovery. A few individuals apparently decide drugs are more important than anything else in life.

Sometimes a pharmacist begins the recovery process before the Board has completed its initial investigation and obtained sufficient evidence to act against the individual's license.

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*The earlier a pharmacist  
begins the recovery  
process, the easier it  
is for everybody.*

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Being in recovery does not protect an individual from disciplinary action by the Board and does not change the violation of the law that occurred prior to recovery. If these violations come to the Board's attention, the disciplinary process will be implemented. However, being in recovery in a recognized program and complying with a contract with the Pharmacists Rehabilitation Committee makes it more likely that

a pharmacist's license will not be summarily suspended.

The most important factor in determining if a pharmacist's license will be suspended on an emergency basis is whether or not the public is in danger. If a pharmacist is known by the Board to be in compliance with his or her rehabilitation contract, it is less likely that the public is in danger. If the pharmacist is an in-patient, it is extremely unlikely that the public is in danger.

### Board Charges

Once the Board issues charges, the pharmacist becomes personally involved in the disciplinary process. The charging document notifies the pharmacist, who is now referred to as the "respondent" of the following:

- Which law or laws the Board believes the respondent has violated.
- What he or she did to violate those laws.
- When the pre-hearing conference will be held.
- When the hearing will be held.
- A recommendation that the services of an attorney be acquired as soon as possible.

No pharmacist wants to see this kind of document with his or her name on it. However, a pharmacist who is in recovery and complying with his or her rehabilitation contract has less to fear than one who has a substance abuse problem that is not under control with documented monitoring.

### Representative Situations

Let us compare two representative situations:

Pharmacist ABC is in recovery, has a documented track record of sobriety, and is fully complying with his rehabilitation contract. Pharmacist ABC telephones his Committee contact to notify him of receipt of the charges. The Committee is ABC's advocate,

providing emotional support, and is able to provide documentation of ABC's recovery to the Board at the appropriate time. ABC has others who are part of his support system. ABC may also contact an attorney.

Pharmacist XYZ on the other hand either knows she has a substance abuse problem or is trying to deny this to herself and others around her. She has not received the help she needs or has relapsed. XYZ knows she's in deep trouble now. Usually XYZ will act in one of three ways. She may acknowledge she has a problem and begin treatment immediately, she may deny his substance abuse, or she may postpone the decision until the Board requires her to be evaluated.

If XYZ goes to see an attorney, the best advice the attorney can provide is to strongly urge XYZ to be evaluated immediately by an expert recommended by the Pharmacists Rehabilitation Committee. Then XYZ should carefully and completely follow through on the recommended treatment plan. The longer someone

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*A pharmacist in recovery  
has less to fear from  
the disciplinary actions  
of the Board*

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is in recovery that is documented by a recognized therapist, the better are his or her chances that the Board will accept the existing plan as appropriate. If XYZ waits until after she goes before the Board to be evaluated and obtain treatment, she does not know what to expect. She does not know what the evaluation will indicate or the type of treatment that will be recommended.

Although ABC and XYZ will each be meeting with the Board of Pharmacy, ABC has a head start on recovery and a much better idea of what to expect. The time for the pre-hearing conference arrives. ABC and XYZ do not know it, but they

are scheduled for the same day, only at different times.

### Pre-Hearing Conferences

Both pre-hearings are the same. One or two Board members and its executive director represent the Board. After introductions, the Board's executive director explains the format for the meeting. The prosecutor explains the case against the pharmacist, detailing the allegations the prosecutor would expect to provide if a formal hearing were to be held. The pharmacist or his attorney explains the pharmacist's view of the situation. The Board representatives ask questions of the pharmacist to understand from the pharmacist's perspective the events that led to the charges. The pharmacist has every opportunity to explain his position. While the



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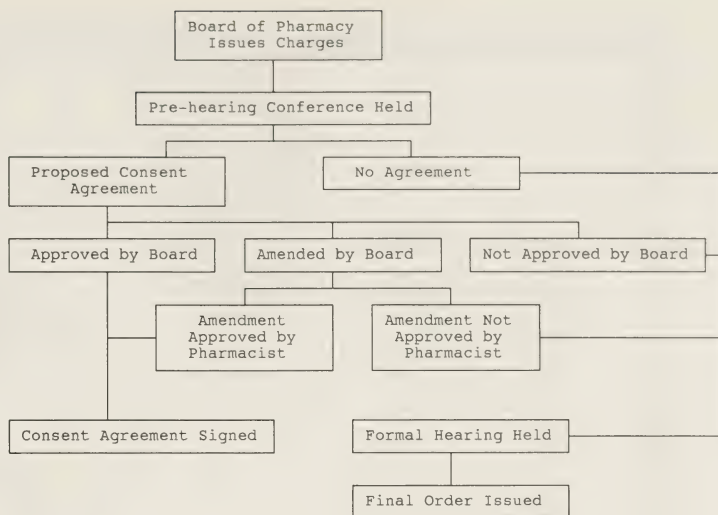
format for both pre-hearings is the same, because the two pharmacists' situations are quite different, the pre-hearing experiences will also differ.

ABC has a contract with the Rehabilitation Committee. ABC has recently been fully evaluated by a substance abuse expert known to the Board, and provides a report with recommendations from the expert. The recommendations indicate whether or not ABC should work. If employment is appropriate, then the report indicates any special conditions or limitations to that employment. Also specified is appropriate therapy, and any other recommended actions to support the recovery process or monitoring specifically designed for ABC. In addition, ABC provides a copy of his contract with the Rehabilitation Committee and a letter from the Committee with its recommendations.

This information provides the basis for the Board's decision. Whether ABC is allowed to work is not based on how "bad" he is, but how sick he is; in other words, where ABC is in the recovery process. While there is no guarantee that the Board will agree with each and every recommendation presented, this could easily happen. It is also possible that the Board's proposed resolution to the situation would incorporate all of the recommendations plus some additional monitoring. It is unlikely that the meeting would hold many surprises for ABC. It is likely that the Board's representatives and ABC would be able to negotiate a consent agreement to present to the full Board for its approval.

### Consent Agreements

If the Board accepts the proposed consent agreement, the document is signed and becomes an Order of the Board. The matter is formally resolved without ABC going through a hearing, which is similar to a trial. If ABC had been sober and in



### Board Disciplinary Process

recovery for quite some time, with recognized authorities expressing confidence in his ability to practice on probation, he might negotiate the following typical agreement. His license could be suspended with the suspension immediately stayed which would allow him to work on probation under a number of conditions such as the ones listed here:

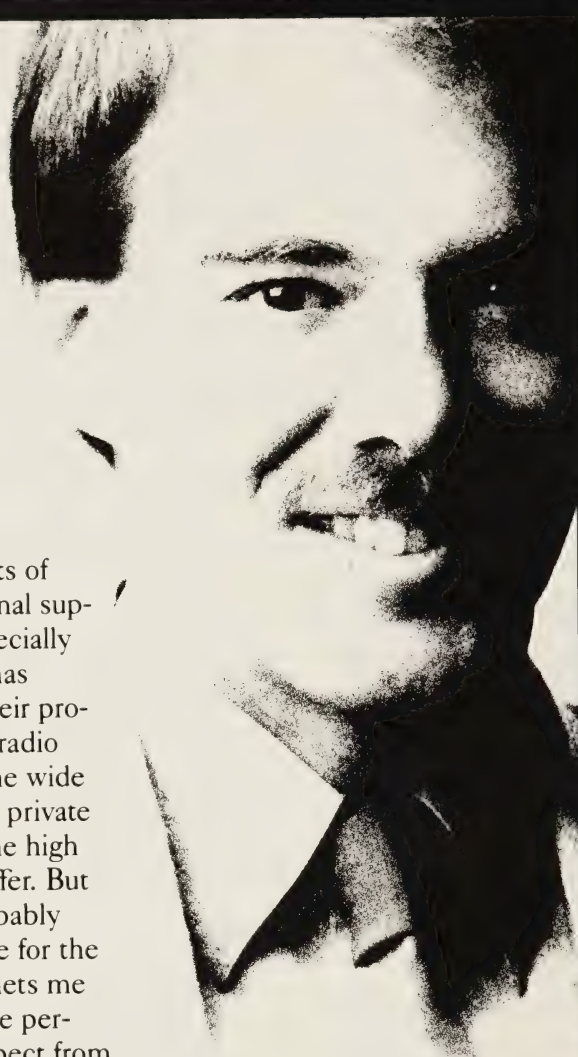
- Any and all pharmacy employers of pharmacist ABC provide the Board with a statement that they have received a copy of the Order and agree to comply with the conditions pertaining to the employer.
- All pharmacy employers must provide quarterly reports to the Board.
- The Rehabilitation Committee and the therapist must also agree to comply with the conditions of probation and provide quarterly reports.

- A specific number of weekly observed urine screens are reported to the therapist who includes the results in quarterly reports. However, positive results are immediately reported to the Board.

- Pharmacist ABC includes in his personal quarterly reports verification of required attendance at Alcoholics Anonymous and/or Narcotics Anonymous.

Orders that allow a pharmacist to work on probation include a statement indicating that if the Board believes the pharmacist has violated any condition of probation or the Pharmacy Act, the Board may take immediate action to suspend the pharmacist's license without a hearing. However, the pharmacist has a right to a hearing within thirty days of the Board receiving a written request.

Generally, the Board does not want a pharmacist in recovery to work as a floater. A stable work environment provides better



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monitoring and support for recovery.

The Order will also specify when the person on probation may petition for reinstatement. Reinstatement without conditions is never automatic. Petitioning the Board two years after the date of the Order is most common; however, that time could be set sooner or later. Reinstatements will be covered in detail later. But first, let us return to Pharmacist XYZ to see what happens at her pre-hearing.

XYZ admits to taking some Halcion tablets, without prescription, for her own use during several weeks at a time of family crisis. XYZ says this was an unusual situation and she does not have a substance abuse problem. XYZ has had no legal problems in the past and brings with her letters of recommendation from important people stating that XYZ has done valuable work in her community.

XYZ and the Board representatives work out a proposed consent agreement that allows XYZ to practice on probation providing that she is evaluated and the evaluation indicates that it is appropriate for XYZ to practice. XYZ agrees not to practice while awaiting the outcome of the evaluation. The evaluation is to be conducted by an expert chosen by the Board. XYZ agrees that if the evaluation indicates that she should not be practicing pharmacy, a new agreement would be needed. The basis of the agreement would be the results of the evaluation and its recommendations. Any agreement would include a requirement for XYZ to sign a contract with the Rehabilitation Committee consistent with the recommendations.

Later, XYZ's evaluation is received and it indicates her life is out of control and she has a significant substance abuse problem.

XYZ needs to be admitted to an in-patient facility immediately.

The Rehabilitation Committee then works with XYZ to help her accept the recommendations and enter an appropriate treatment facility. The Board representatives and XYZ agree to postpone any long-term decisions about XYZ's license until after she completes her in-patient treatment and her discharge report with recommendations is reviewed. During that time XYZ continues her voluntary agreement not to practice. At some point XYZ will meet with Board representatives again to negotiate an agreement consistent with her recovery status. In the meantime, she is getting the help she needs and the public is protected.

It is easy to see that ABC is in a much better position to interact with the Board than XYZ. However, they both receive the help they need. It is only a matter of timing and of who is controlling the process.

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Now let us return to the disciplinary procedure. The Board has a proposed consent agreement for its consideration. Usually it will be approved as presented. Occasionally the Board will suggest a modification. Once the Board and the pharmacist agree, the consent agreement is signed and the matter is resolved without a hearing. Most of the Board's disciplinary cases are handled by consent agreement. The pharmacist always has a right to a formal hearing before the full Board, but it is extremely unusual for one to be requested.

### Probation

After the consent agreement is signed, the pharmacist begins working on probation. This is not the end of the process; this is a new beginning. At the Board office, the consent agreement is reviewed and a chart created indicating each document to be received and the date it is due. As each monitoring report is received, the date received is recorded next to the date it is due. At any time it is easy to see if the pharmacist is complying with the consent agreement. It is recommended that each individual on probation create a similar chart for himself or herself. It is the responsibility of the person on probation to assure that all conditions of the Order are met. If the employer or the therapist does not submit a report as required, neither of *their* licenses is on the line. Sometimes it may be necessary for pharmacists on probation to remind one of their monitors to send in a report. This is just one responsibility of being on probation.

All Board Orders require a pharmacist on probation to provide a copy of the Order to any and all pharmacy employers. Each pharmacy employer must agree to comply with the conditions pertaining to the employer, usually in the form of quarterly reports to the Board. Naturally, this requires the pharmacist to explain the situation to

prospective employers. It is recommended that the pharmacist practice interviewing techniques. The Rehabilitation Committee contact, the therapist, or another supportive individual could assist in this role-playing activity.

The Board's executive director receives all of the monitoring reports and is available to answer questions about the process. Sometimes employers ask what is expected of them. The answers help them to understand their responsibilities and how the probationary requirements support them and the pharmacist. The Order becomes a safety net and an early warning system. It seems that a pharmacist on probation in compliance with all probationary conditions is a safer bet not to be using drugs than a pharmacist who has had no personal contact with the Board.

### Reinstatement

All of the Board's Orders are set up so that the person on probation must petition the Board for the probationary conditions to be removed. Reinstatement without conditions is not automatic. If the person on probation never petitions for removal of conditions, the conditions continue forever. An Order will indicate when the pharmacist may petition for reinstatement. A petition is just a letter making a request.

It is recommended that a pharmacist prepare for reinstatement by taking the following steps. The pharmacist reviews the Order and verifies that all conditions of probation have been satisfied. The pharmacist discusses the appropriateness of reinstatement with everyone monitoring his probation as well as family members or others supporting his recovery. Then he determines his best course of action. He may consider no change in the Order, modification, or elimination of some of the terms in the Order, or full reinstatement without conditions. The Board

expects that the pharmacist, his therapist and the Rehabilitation Committee will agree on his choice.

The pharmacist writes a letter to the Board making his request. It is best for the pharmacist to arrange for each individual or group monitoring his progress to submit to the Board a recommendation supporting his request. Then the pharmacist is scheduled to meet with the full Board at its next meeting.

At the Reinstatement Meeting the Board asks the pharmacist to explain:

- The problem that initially brought him before the Board.
- What has happened during his probation.
- How his life is different now than when he first came to the Board's attention.
- The pharmacist's request.
- His plan for the future.

The pharmacist has an opportunity to share his thoughts. It is recommended that he include an explanation of how he has complied with each condition of the Order, a summary of the recommendation of each of those monitoring his progress, and any other information that will provide the Board with substantial reasons to honor the pharmacist's request.

Then the pharmacist leaves the room. The Board discusses the request and considers: whether or not the pharmacist fulfilled the conditions of probation; whether those monitoring the probation support the pharmacist's request; if the request is reasonable considering the pharmacist's present evaluation; and whether the pharmacist's support systems are adequate to continue to support his recovery.

If the pharmacist has complied with his Order and those monitoring his progress support his request, it is likely that the request will be granted. A decision will be made and the pharmacist will be notified of the outcome.

## Personal Observations

Now that we have walked through the disciplinary process, as the Board's executive director I would like to share some of the comments that have been made to me as well as share my own personal thoughts with you.

I believe a pharmacist who postpones getting help until he meets with the Board is asking the Board, instead of the Rehabilitation Committee, to conduct his intervention. Although the Board has an excellent process for handling these cases, I believe a person is not exercising good judgement to wait for the Board to conduct the intervention. It is always better to begin recovery when substance abuse is treated *only* as an illness, not as a legal problem.

I feel that the Board's actions are beneficial to pharmacists, their families and to the community. Having participated in the process for a number of years, I have seen people go from their lowest point in life through the recovery process and stay sober for years.

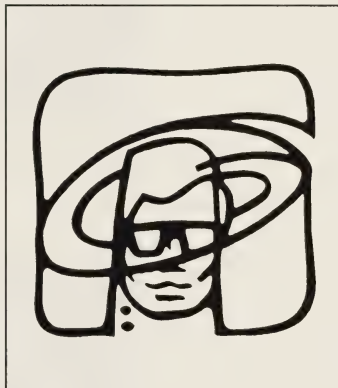
One pharmacist whose pre-hearing was a number of years ago said at that time he thought it was the end of his life. He was required to be out of practice for a significant period. Later he was placed on probation with a number of conditions. Subsequently, his license was reinstated without conditions. He continues to be a model pharmacist, helping others. Recently, he reflected on the day he agreed not to practice pharmacy. He said, "That day was not the end of my life....it was the beginning."

The importance of the Board's process is best expressed in the words of another pharmacist who said to me, "I thought this was about saving my license; I realized later it was about saving my life." ■

# Addiction is a Family Disease

*Anonymous*

What everyone seems to know about addiction focuses on the addict. His abuse of drugs, the trouble legally or socially it brings and the stigma attached to it. What most people do not see or realize is the effect on all the people around the addict. This is a short story of the addict in our family.



As a pharmacist, I was well informed in drug knowledge, both use and abuse. As a parent I loved my children. When my teenage son began his trip down the path of alcohol and illegal drug use I began my trip down the path of denial. For almost ten years our family denied the presence of a monster in our midst and allowed addiction to tear our family apart. Our daughters hated their brother and I refused to admit that I and the family would be better off without him around. Because we felt a need to appear to have our lives in order, the inability to be honest with ourselves and those around us, took us deeper and deeper into isolation. Constant lying

to everyone, friends and family, that everything was alright.

The overwhelming thing for me was the isolation. The knowledge that I couldn't share what was going on with me and carrying the guilt that as a parent I could not do the right thing to save my child. Nothing worked. Here I was in a situation that I did not cause, could not control and definitely could not cure. I was a co-dependent to his disease along with my spouse, his sisters, grandparents and friends. In a typical situation, the addict will adversely affect the lives of five other people. In our case ten people were co-dependent causing a negative impact on their spiritual, emotional, physical, financial and social aspects of their lives.

Help finally came, but only after a legal crisis. An inpatient rehab program with months of after care, coupled with a relapse has finally put the addict into an active recovery mode. The family is finally beginning to face the disastrous years and hopefully is on the road to recovery itself. We are now ten years after the original inpatient rehab program and about 17 years since the beginning of my son's drug use.

If you can identify with any of my story, I can tell you there is help for you. The biggest and most important step is making contact for the first time with someone who has been through the same hell, who will listen without judging and who understands. ■

# Important figures in diabetes care



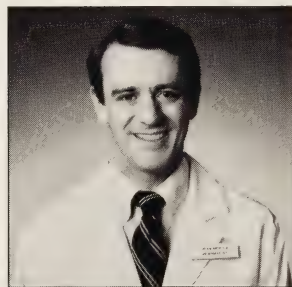
Diabetes is the **No. 7** cause  
of death in the US<sup>1</sup>

---



Diabetes is the **No. 1** cause of new  
blindness in persons aged 20-74<sup>1</sup>

---



Pharmacists see patients with diabetes  
**5** times more often than do physicians.  
These customers spend 3 to 8 times more  
annually in the pharmacy than persons  
without diabetes.<sup>2</sup>

---



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Your Lilly sales representative will visit you soon with  
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can offer you and your customers with diabetes.

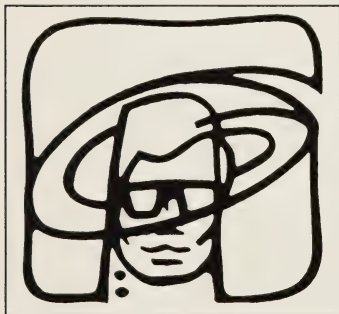
1. *Diabetes Surveillance, 1980-1987*. Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes*. Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

## Clues to Impairment in Pharmacists

In order that you may be better able to recognize an emerging problem in a colleague or friends, we are publishing these clues to chemical dependency and impairment. Clues listed in *italics* may be symptoms of early impairment.

### Home and Family

*Medicinal use of alcohol or drugs.*  
*Mood swings or inconsistency.*  
*Behavior excused by family or friends.*  
 Extreme temper.  
 Heavy drinking.  
 Drinking of drug using activities more important than other activities.  
 Children neglected, abused or in trouble, often with drugs.  
 Fights, arguments and violent outbursts.  
 Sexual problems.  
 Withdrawal, isolation and fragmentation of social and family life.  
 Financial problems.  
 Spouse in psychotherapy or taking psychoactive medication.  
 Lack of problem resolution.  
 Separation or divorce



### Work Life

*Overwork.*  
 Disorganized schedule.  
 Spasmodic work pace.  
 Unreasonable behavior.  
 Inaccessible to patients and employers.  
 Prescription errors.  
 Patient complaints.  
 Frequent absences.  
 Decreased workload and tolerance.  
 Frequent days off for vague reasons.  
 Taking sexual advantage of co-workers or customers.  
 Filling illegal prescriptions.  
 Taking and/or using drugs from pharmacy without a legal prescription or without follow-up by a physician.  
 Taking and selling drugs to others or giving them to family or friends.

### Employment Applications

Frequent job changes or relocations.  
 Unusual medical history.  
 Vague letters of reference.  
 Inappropriate qualifications.  
 Time lapse unexplained in work.  
 Inappropriate job now.  
 Refusal of physical exam or spouse interview.

### Physical Status

*Insomnia.*  
*Personality and behavior changes.*  
*Amnesias.*  
 Multiple physical complaints and illnesses.  
 Frequent ER visits and hospitalizations.  
 Inappropriate tremulousness or sweating.  
 Poor hygiene and appearance.  
 Long sleeves in warm weather.

### Pharmacy

Often late, absent or ill.  
 Decreased work performance.  
 "Pharmacy gossip".  
 Unavailability.  
 Alcohol on breath while in pharmacy.

### Friends and Community

*Neglected social commitments.*  
*Embarrassing behavior.*  
 Personal isolation.  
 Overreaction to criticism.  
 Exaggerates work accomplishments and finances.  
 Drunk driving arrests.  
 Legal problems.  
 Lessening of ethical values.  
 Unpredictability or unreliability. ■

## News from Around the State

### *Pharmacy School Commended*

The external Evaluation Team that spent two days at the School of Pharmacy in February as part of the American Council on Pharmaceutical Education accreditation process has issued a report commending the School for its comprehensive study of professional education. It endorsed the School's decision to consolidate its professional programs into a single entry-level doctor of pharmacy program.

Highlights from the final report of the ACPE Accreditation Team include:

"Since 1985, the School has expanded substantial time and energy in the study of its two entry-level professional programs, the baccalaureate in pharmacy and the doctor of pharmacy, so as to insure educational preparedness for the general practice of pharmacy.

Curricular study and strategic planning efforts have revealed an already overburdened and compacted baccalaureate in pharmacy curriculum, along with a need for additional content to satisfy stated objectives and provide for practice competence. These planning activities resulted in a decision to consolidate the two entry-level programs into a revamped doctor of pharmacy program as the School's only professional program offering.

The Evaluation Team was impressed by the thorough strategic planning and the comprehensive study of professional program offerings undertaken by the School.... and finds the School's decision regarding its future professional program offering to be an appropriate and sound educational policy for this institution.

The Evaluation Team encourages

the School to move ahead with its plans for programmatic transition as quickly as possible. The School should utilize its statement of objectives and strategic plan as a blueprint for curricular planning. Broadly-based planning for the new professional program and related activities, such as a non-traditional degree program option, is encouraged."

Members of the Evaluation Team included: William Adams, Maryland Board of Pharmacy; Richard deLeon, University of Michigan; Dick Gourley, University of Tennessee; John Mauger, University of Nebraska; John Vandel, community pharmacist, ACPE; Jeff Wadelin, ACPE.

Contributed by David Knapp, Ph.D.

### *New Pharmacies*

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Drug Counter - Bel Air  
104 Plum Tree Road, #113  
Bel Air, Maryland 21014

F & M Pharmacy #128  
6515 Dobbins Road  
Columbia, Maryland 21045

Institutional Pharmacy Services  
Moore's Mill & Conowingo Road  
Bel Air, Maryland 21015

K-Mart Pharmacy #9524  
161 Big Elk Mall  
Elkton, Maryland 21921

Kaiser Permanente - Rosedale  
9105 Franklin Square Drive  
Baltimore, Maryland 21237

Rite Aid #2620  
903 East Fort Avenue  
Baltimore, Maryland 21230

Rite Aid #2628  
12108 Central Avenue  
Bowie, Maryland 20721

Rite Aid #2752  
Route 64  
Smithsburg, Maryland 21783

Rite Aid #2754  
2340 University Boulevard  
Adelphi, Maryland 20783

Safeway Pharmacy #817  
116 University Boulevard  
Silver Spring, Maryland 20901

Wal-Mart Pharmacy 10-1674  
1650 Wesel Boulevard  
Hagerstown, Maryland 21740  
Contributed by Leon Weiner, P.D.

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Frederick, Maryland 21701

Best Care  
800 Pershing Drive  
Silver Spring, Maryland 20910

Caremark Pharmacy Services  
1301 York Road  
Lutherville, Maryland 21093

Harford Medical Services  
2105 Laurel Bush Road  
Bel Air, Maryland 21014

Holiday Acres Pharmacy  
Route 4, Box 11  
Smithsburg, Maryland 21783

Winn's Pharmacy  
2540 East Fayette Street  
Baltimore, Maryland 21224  
Contributed by Leon Weiner, P.D.

## Pharmacists' Rehabilitation Committee

### A Report on Nine Years of Service (Part II)

Tony Tommasello, B.S.Pharm., M.S.

Assistant Professor of Clinical Pharmacy, University of Maryland School of Pharmacy

#### Abstract

During roughly nine years of existence the Pharmacists' Rehabilitation Committee (PRC) has been instrumental in the recovery attempts of 62 pharmacists. Fifty-two (84%) have been male and 54 (87%) have been white. Most (56.6%) have received inpatient care at some point in their recovery. The number of pharmacists coming into the program has increased steadily over the nine year period with the highest annual rate of entry being ten cases in 1990. The drugs most frequently mentioned on admission to treatment are narcotics and alcohol, with cocaine and benzodiazepines being close behind and marijuana being rarely identified. The preponderance of cases are self-referred (34%) while the sum of State Board of Pharmacy and employer referrals account for 29% of cases. Close to half (48.4%) of the pharmacists were practicing in community pharmacies at the time of first contact. Of the 62 cases, only four are considered treatment failures. This low failure rate (6.4%) may reflect the ability of coercive yet supportive processes to move people along the road to recovery.

#### Introduction

In part one of this piece, Harry Finke describes the origins of the Pharmacists' Rehabilitation Committee (PRC) and provides a narrative overview of service activities. The purpose of part II is to make a data report on the PRC activities. In the early period of operation the main concern of the PRC was to establish a functional program by; developing linkages with treatment centers to insure access to diagnostic and treatment services, creating a contract agreement between recovering pharmacists and the PRC defining the relationship of advocacy and treatment compliance, and building effective alliances with the Board of Pharmacy and the Pharmacy community. During this start up period, little thought was given to data collection and some information has been lost, making a full report impossible.

As the PRC matured the need for objective reporting became more apparent. To insure confidentiality the PRC has an agreement with pharmacists that upon completion of the 2 year contract all records detailing the treatment process are destroyed. Only a data record of the experience is maintained to allow the PRC to provide this report.

#### Summary of Data

The following table provides a summary of 62 cases handled by the PRC. The age at the time of entry into treatment was recorded in 37 cases. The average age of these pharmacists is 35.7 years. Most of the pharmacists served have been white males and the majority have received inpatient care at some point in their treatment. Four of the pharmacists who signed treatment contracts are considered treatment failures.

#### Summary of Pharmacists

The Pharmacists Rehabilitation Committee  
1983 - February 1992

##### Demographics

Number of contracts signed	62
Average Age (n=37)	35.7 years
Age Range (n=37)	24 - 47 years
Number male	52 (83.9%)

##### Race

White	54 (87.1%)
Black	7 (11.3%)
Other	1 (1.6%)

##### Treatment Received (n=57)\*

Inpatient	35 (56.5%)
Outpatient	23 (37.1%)

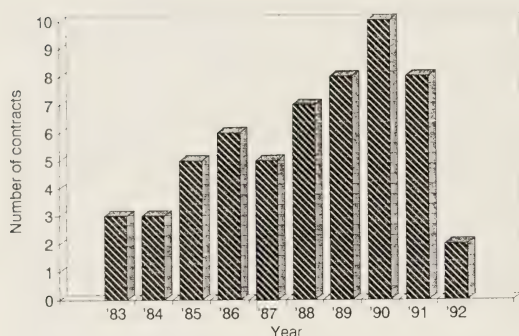
Failed Cases\*\* 4 (6.4%)

\* Pharmacists who received inpatient care at any time during the course of contract are noted in that category. In four cases, treatment received was uncertain.

\*\* At the time of publication those pharmacists who have clearly dropped out of treatment without any indication of returning to therapy.

Figure I shows a steady rise in the number of pharmacists contracting with the PRC since the beginning of the program in 1983. The data for 1992 covers the period from January 1 through February 29, 1992. Contracts with the committee are for a minimum of 2 years with some being extended if, in the opinion of the treatment provider and the PRC members, the pharmacist needs more time under supervised care. At present the PRC is following 26 active cases through a process of treatment provider reports, reports from employers, self reports and regular contact with a PRC member.

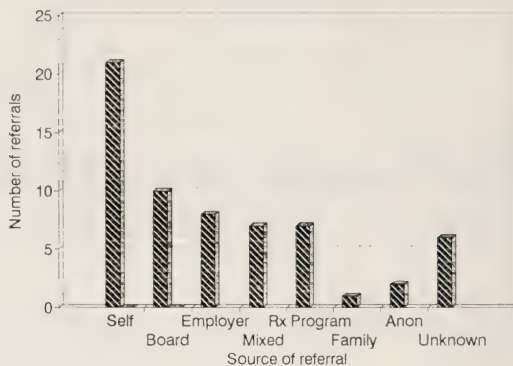
**Number of pharmacists signing contracts by year**



**Figure I**

Figure II indicates that self-referrals are the most common way in which the PRC first becomes aware of a pharmacist in need of service. The referral type is determined by the identity of the first person who provides the name of the pharmacist in need of care. It is our experience that many "self-referred" cases are being prodded by employers to seek help and perhaps would not have come to the PRC if not for that motivation. It's not uncommon for an employer to contact the PRC requesting general information about the program and within a short time a pharmacist calls requesting help. A self referred pharmacist may also come to the PRC with a belief that the Board of Pharmacy is pursuing a case against them and wants the advocacy of the PRC on their side when the case comes up for Board review. Mixed referrals are those in which the pharmacist contacts the PRC and immediately discloses that they are calling under duress by the employer or the State Board of Pharmacy and the identity of motivation is clear.

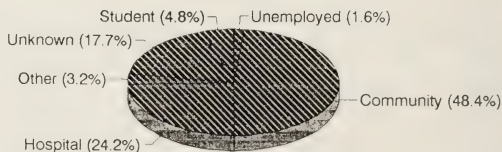
**Referral type**



**Figure II**

Figure III demonstrates that the highest percentage of pharmacists who sign PRC treatment contracts come from a community practice site. The distribution of practice sites among the population of cases seems to be consistent with the distribution of pharmacists in practice sites generally.

**Practice site at entry  
(percent of total)**



**Figure III**

Figure IV is a display of drug mentions on admission to treatment. Some pharmacists identify more than one agent as they describe their drug use history. For instance alcohol dependency alone is identified in only 6 cases while in an additional 12 cases the reported "drug of choice" is alcohol in combination with another drug. Yet in another 2 cases alcohol is sometimes used but not as preferred drug. "Drug mentions" captures all drugs in the pharmacist's history which were problematic at the time of admission. Surprisingly narcotics surpassed alcohol by a narrow margin.

# Ignorance of the Law.....

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## Implications

Based on the widely quoted 10 percent prevalence of alcoholism and other chemical dependence in the general population, we would expect that somewhere between 400 and 600 pharmacists in Maryland are in need of treatment. It is clear that the PRC is not reaching every case of chemical dependence among Maryland Pharmacists. Those who are able to identify treatment resources on their own initiative may not come to the attention of the PRC. Some of these cases may eventually be captured by the PRC as clinicians recognize the advantage of the treatment contract and advocacy role that the PRC provides.

An important role of the PRC is that of guiding pharmacists to the most appropriate treatment for their stage of chemical dependency progression. An individual seeking treatment on his own may waste a considerable amount of time pursuing treatments that are ineffective for his particular situation. This not only prolongs the period of illness before starting treatment but may hinder treatment efficacy through a mismatch between treatment needed and treatment received.

### Drug mentions on admission (number of mentions)

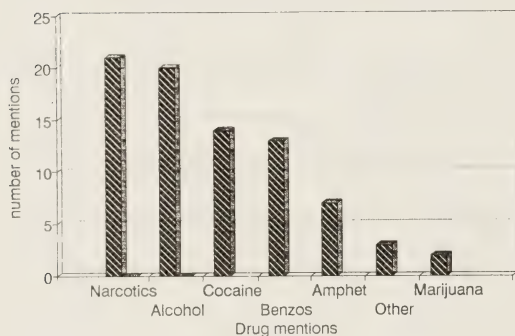


Figure IV

The PRC does not deliver direct addiction services to the recovering pharmacist. Rather, the role of the PRC is to provide advocacy, to support the pharmacist during periods of despair, and to seek ways of maximizing treatment compliance. The wide array of treatment needs of the recovering pharmacist is only partially acknowledged in the drugs they use. Thus the cocaine dependent pharmacist has different needs than the alcohol dependent pharmacist based exclusively on the drug and its effects. Beyond these considerations is the clinical realization that chemical dependency is a multidimensional illness. It affects not just the individual, but his family, friends, colleagues, employers and every other social contact in his life. The pharmacist's self-esteem is another victim of the disease. Attending to

each of these dimensions in recovery is difficult and time consuming. Maintaining motivation during the first few months of therapy is often difficult. Initially it appears that the pharmacist stays in treatment because of the contract agreement. Over time however, there is a transition from the external control of the PRC contract to the individual's recognition that treatment is essential to survival.

The transition in locus of control is clinically evident. The pharmacist loses his resistance to many of the PRC contract stipulations and often seeks additional treatment services on his own. For instance a pharmacist and his wife may enter couples therapy to address discontent in their marital relationship caused by chemical dependence. The change is unpredictable, often abrupt, and is always accompanied by an improvement in prognosis.

This speaks to the issue of readiness to return to practice. One of the compelling questions facing health professionals recovery programs is the concern about job related relapse. The employer may consider the risk of relapse along the lines of poor job performance, CDS diversion, and prescription error liability. The therapist is likely to think more in clinical terms of return to drug use, progression of the disease, and further disruption in the pharmacist's life. By anyone's point of view relapse is a tragic backslide into the addiction with the subsequent risk of a freefall deterioration.

In most cases the recovering pharmacist is prohibited by contract from returning to the dispensing arena for the first 3 to 6 months of treatment. While there is no risk-free practice re-entry guarantee, the probability of relapse can be minimized by early close supervision which is eased as level of trust between employer and pharmacist increases and the pharmacist takes on more responsibility. Therapy sessions during the initial weeks to months of re-entry often focus on the experience of the pharmacist as he confronts the challenges of high stress, drug availability, and the environmental cues associated with past drug use. The insights gained in treatment may lead the recovering pharmacist to make a change in his career path, opting for practice sites where dispensing duties are non-existent or access to CDS is not present. Without a substantial investment in a formal educational program these opportunities are limited. Employers can ease the stress of re-entry and reduce the risk of relapse by recognizing the need for a flexible schedule in light of the treatment demands facing the recovering pharmacist.

Avoiding treatment failure could be considered the single most important objective of any therapeutic program. Identifying treatment failure is easier than defining treatment success. The PRC maintains an optimistic perspective on recovery recognizing that an individual may need more than one attempt at treatment. However there have been 4 cases in which all attempts to initiate and sustain recovery were rejected by the pharmacist in spite of the consequences involved. Another point of view is that the treatment system needs

improvement and the most difficult cases will continue to be lost until strategies are developed to effectively deal with them.

### Summary

The factors thought to play a role in the development of impairment among health professionals include; genetic predisposition, environmental exposure, drug availability, stress and poor coping skills, lack of knowledge regarding chemical dependency especially self-assessment skills, denial, and the absence of effective prevention strategies(1). Since these shortcomings are not likely to be resolved in the near future, the development of more effective treatment approaches is a logical course of action. The pivotal role of the PRC in providing a confidential and efficient conduit to care coupled with the offer of advocacy in response to contract compliance appears to work well. Health professionals recovery programs generally have a better record of treatment success than their general population counterparts. Sustaining a PRC with contributions of both volunteer time and financial support is a wise investment in the physical and emotional health of the profession.

### References

1. Talbott GD, Gallegos KV, Wilson PO, and Porter TL. The Medical Association of Georgia's Impaired Physician Program, Review of the first 1000 physicians: Analysis of specialty. *JAMA* 257: 2927-2930 (1987)

## Coming in Next Month's Issue



### Results of the 1992 MPhA Salary and Benefits Survey

### A Recap of MPhA's 1992 Legislative Activities



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## President's Commentary

*Ilene Zuckerman, Pharm.D.*



This issue of *The Maryland Pharmacist* deals with a sometimes delicate subject: chemical dependency and impairment of pharmacists. Addictive disease affects all aspects of society, including our own profession.

I'm sure that some of you have experienced the situation of confronting an impaired colleague. Unless we have been properly educated about the physical and psychological disease of addiction, it is unlikely that we will feel confident, competent or comfortable in initiating interventions. Recognizing impairments, understanding appropriate referral and treatment techniques, and discouraging enabling behaviors of co-dependents are skills each of must learn.

The Pharmacists Rehabilitation Committee is a coordinated effort by the Maryland Pharmacists Association, the Maryland Society of Hospital Pharmacists and the University of Maryland School of Pharmacy to reach out to chemically dependent members of our profession. It is a volunteer organization funded by contributions from MPhA and MSHP members with staff support provided by both MPhA and the School of Pharmacy.

The Pharmacists Rehabilitation Committee is a group of dedicated, trained pharmacists with expertise in addiction management. I cannot stress enough the positive impact the work that these pharmacists have had on confronting impairment in our profession. Committee members have and continue to perform outstandingly in identifying problems, referring pharmacists for treatment, providing follow-up support, and maintaining confidentiality. They give compassion and understanding to the dependent when no one else will or can; they provide a structured treatment regimen that helps rescue them from their disease and from themselves.

I am sure that after reading this issue, your ability to recognize signs of impairment and to take action will be improved. I urge you to include the Pharmacists Rehabilitation Committee as part of your plan to help your fellow pharmacist in need.

The facing page is designed to help raise funds for the Pharmacists Rehabilitation Committee. Any contribution you can make will enable the Committee to educate pharmacists about chemical dependency in addition to aiding those among us who are impaired. More important than your money is a commitment of your time. If you are interested in serving on the Committee in any capacity -- taking part in interventions, coordinating educational programs for pharmacists, or helping a fellow colleague on the road to recovery -- I urge you to contact the Committee at (410) 727-0746 or (410) 328-7513. ■



## Ignoring the Problem Won't Make it Go Away

You wouldn't ignore the needs of your patients with diabetes, hypertension or arthritis? Why pretend that your impaired colleagues don't exist or don't need your help?

You can help the Pharmacists Rehabilitation Committee continue its years of successful aid to Maryland pharmacists by making a contribution. Send your check or money order *today!*

Yes, I want to help, here is my \$ \_\_\_\_\_ contribution.

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Send your contributions to  
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650 West Lombard Street  
Baltimore, Maryland 21201-1572

# Continuing Education

## Continuing Education Quiz

May 1992 -- Pharmacists Rehabilitation

Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by November 30, 1992. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

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Is this program used to meet your mandatory CE requirements?  
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☐ Yes    ☐ No  
☐ Yes    ☐ No

The questions for this month's quiz are drawn from articles throughout the May 1992 journal.

1. All of the following are true about the Pharmacists Rehabilitation Committee except:
  - a. it is an advocacy group
  - b. it is a licensing and regulatory body
  - c. involved in getting treatment for dependent pharmacists
  - d. have been in existence for nine years
2. How many committee members must be present at the interview with an impaired pharmacist?
  - a. one
  - b. two
  - c. three
  - d. four
3. Who can contact the PRC about a chemically impaired pharmacist?
  - a. the pharmacist
  - b. employer of the pharmacist
  - c. customer of the pharmacist
  - d. all of the above
4. The Board of Pharmacy requires reports on impaired pharmacists on probation:
  - a. twice a year
  - b. once every quarter
  - c. once every two months
  - d. every month
5. Which is not a clue to chemical impairment?
  - a. often late to work, absent or ill
  - b. amnesia
  - c. increased workload and tolerance
  - d. financial problems
6. When the Board of Pharmacy investigates a pharmacist for impairment problems, which occurs first?
  - a. consent agreement
  - b. pre-hearing conference
  - c. reinstatement
  - d. probation
7. Which of the following work conditions would be most optimal for a recovering pharmacist?
  - a. a pharmacy that fills 100 Rx/day
  - b. a pharmacy that fills 600 Rx/day
  - c. a mail order pharmacy establishment
  - d. being a floater between 3 busy pharmacies
8. Which of the following is false concerning the contract between the PRC and the impaired pharmacist?
  - a. the pharmacist is followed by one committee member during the contract period
  - b. upon completion of the contract, all committee records, except for the contract, are destroyed
  - c. the contract period for treatment is one year
  - d. the PRC can extend the contract period
9. The most often abused substances by pharmacists are:
  - a. narcotics, alcohol and cocaine
  - b. alcohol, narcotics and benzodiazepines
  - c. cocaine, benzodiazepines and amphetamines
  - d. narcotics, cocaine and marijuana
10. The majority of referrals to the PRC come from:
  - a. family members
  - b. colleagues
  - c. Board of Pharmacy
  - d. impaired pharmacists themselves

# Classified

**THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION**, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (410) 358-7036.

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# The Maryland Pharmacist

VOL. 68

JUNE, 1992

NO. 6



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# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association  
650 West Lombard Street, Baltimore, Maryland 21201-1572

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## President's Commentary

*Ilene Zuckerman, Pharm.D.*



I ran into an acquaintance the other day; she asked what I did for a living. I told her I was a pharmacist. She is a speech pathologist. We got into a conversation about our careers, and she questioned me: "What is it exactly that you do? You just count and stick labels on bottles, right?" She was dead serious. This woman had absolutely no insight into what our profession is all about.

Of course, I attempted to explain the professional responsibilities of pharmacists, giving examples of drug interactions, adverse drug reactions, and treatment failures. She claimed to never have had an interaction with a pharmacist. I countered that perhaps that is because she is a young, healthy woman with no need for an in-depth therapeutic intervention by a pharmacist.

Something is wrong here. This woman questioned the value of my profession. Why do I not doubt the value of a speech pathologist? or a dentist? or a physical therapist?

It is easy for me to preach to you the significance of our profession. But you are the wrong audience. It is the public, your customers, that do not always readily identify our merit. But can we blame them? What have we done to document our performance?

A pharmacist-owner commented to me that he hears stories from his patients about their fears of switching doctors or dentists when their insurance changes. The patients do not have the same fear about switching pharmacists. The pharmacist-owner contends that this lack of concern about switching pharmacists is because of this: a dentist has a complex, sophisticated skill; you don't want the dentist to drill the wrong tooth, or drill too deep. A pharmacist isn't dealing with situations that can lead to morbidity or mortality.

We have performed such an excellent job dispensing, almost to perfection, that it is taken for granted. Overall, there are few reports of dispensing errors, and even fewer dispensing errors that have led to harm. Most people feel confident that they can go to any pharmacy and be assured of a certain standard of care; i.e., being given the right drug, and having the opportunity to ask any questions about the prescription. But now it is time to go beyond the "basics" of pharmacy practice. I know that some of you claim that you already are practicing at a higher level. If that is true for you, great! But are you documenting what you are doing?

I am certain that many of you have stories about how your professional interaction made a difference in patient care, perhaps even in preventing a hospitalization, or saving a life. Sure, these are not everyday occurrences. One of my pharmacist mentors once taught me that a technician can fill 75% of a pharmacy's prescriptions without any problem; it's the other 25% that requires a pharmacist's unique (and yes, complex and sophisticated) knowledge and skill.

Recently, pharmacist representatives met with HMO representatives, to discuss the consumer access issue. One of the HMO pharmacists made an observation that community pharmacists do not provide the cognitive services that they (we) claim to provide. Certainly, we can give all anecdotal stories

of how our "cognitive services" have impacted patient care. But we need more than just anecdotes. We need clear, concise documentation about these interactions. This documentation should be detailed enough to convince a payor the value of the service. Remember, if it wasn't documented, it wasn't done.

We lost the "consumer access" legislation in Annapolis this year. But perhaps it is our own fault. Perhaps, then, it is time to take an introspective examination of our practices, and ask: "How is my pharmacy practice unique? Why should a patient (or HMO or benefit administrator) prefer my pharmacy over another?" I am confident that you are able to answer these questions. The next step is to communicate your response to your patients, potential patients, legislators and third-party payors. ■

## MPhA Election Results

As President of MPhA, it gives me great pleasure to report the results of the 1992 MPhA Elections. More than 45 percent of the membership returned their ballots -- the highest voter turn-out in the past decade. Your new officers and trustees will be installed at the 110th Annual Convention in Ocean City on June 17, 1992.

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## Dickinson's Pharmacy

Jim Dickinson

*The Power Pharmacist.* Necessity, they say, is the "mother of invention." So, faced with the wholesale slaughter of a community necessity -- thousands of local pharmacies -- by third party marauders and government agencies, the profession has invented a new breed, the Power Pharmacist.

The Power Pharmacist has a broken with the past and embarked on a new mission: building dependencies.

He or she will do anything to make a patient dependent on his or her pharmacy -- whether for prescriptions, OTC specialties, lottery tickets, newspapers, gardening tips, or ...

Essential equipment in the Power Pharmacy is a computer with modem and word-processing software (a desirable option is desktop publishing software), and a fax machine. These facilities make it a simple matter to issue news releases electronically to local media, and to conduct direct mail marketing/public relations campaigns.

It goes without saying that the Power Pharmacist is an active member of his or her local and state pharmacy association, and coordinates outreach activities with them.

Thus equipped, the Power Pharmacist converts multiple patient dependencies into political and economic dependencies -- using the pharmacy as a communication pipeline into the community for such outreach enterprises as voter registration, cholesterol screening and waste recycling.

By linking these good caused to local politicians as patrons, the pharmacy intensifies its vitality and necessity.

Unlike other pharmacists,

thousands of Power Pharmacists around the country are retrieving direct control of their businesses by making their pharmacies the hub of such relationships between constituencies that need and offer each other help.

With interlocking dependencies, the Power Pharmacist is thus automatically better able to refuse third-party contracts and deal directly with patients using trust-based 30-day credit and usual-and-customary pricing.

The Power Pharmacist has lifted his or her practice above the mere transfer of commodities to the exchange of resources, physical and intellectual.

By extending this power through other pharmacies, the Power Pharmacist signals his or her recognition of the fact that other pharmacies are only secondarily competition -- primarily, they are additional points of power in a network of like practices.

Thus, when a local employer contemplates a cost-containing health benefits package that includes mandatory mail-order for maintenance medications, the Power Pharmacist is able to exercise a pincer-like counter-attack.

On one side, the Power Pharmacist has the network-reinforced argument directly with dependent patients that the employer's plan will jeopardize a community health necessity.

On the other side, the Power Pharmacist's network can use political, civic and business leverage directly on the employer to preserve local assets -- namely pharmacy jobs represented in the Power Pharmacist's store and network, and the

communications links that serve such good (essential) causes as voter registration, cholesterol screening and waste recycling.

Because most employers are sensitive to their own business networks, they will think long and hard before adopting cost-cutting strategies that will disrupt them.

The main reason that local employers continue to adopt mail-order drug programs and plans that confine employees to in-house HMO pharmacies is that nobody has adequately pointed out the likely consequences to them.

In other words, those employers have not dealt with Power Pharmacists.

Why aren't there more Power Pharmacists? Like other people, most pharmacists don't like change; they know something needs to be done, but day-to-day survival come first.

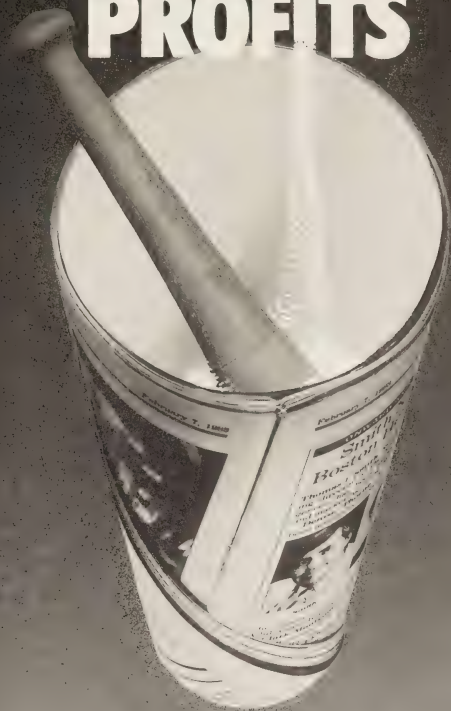
Unless the pharmacy is suddenly confronted with the catastrophic loss of a large block of patients, the gentle erosion of one or two patients at a time to mail-order isn't enough to catalyze the owner into action.

Little by little, almost without noticing, the ordinary pharmacist loses ground while the Power Pharmacist gains it. It has been going on for centuries, in all fields of human endeavor.

My kingdom for a horse, said the king, as the enemy finally overwhelmed him. ■

This feature is presented on a grant from "Dickinson's Pharmacy -- The Independent Voice," a professionally stimulating 8-page monthly newsletter available from Ferdic, Inc., P.O. Box 848, Morgantown, WV 26507-0848 at an annual subscription fee of \$45.

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## The 1992 Legislative Session

Robin Shaivitz, MPhA Lobbyist

The Maryland Pharmacists Association worked very diligently this session on its issues. This year's session turned out to be one of the most difficult session we've ever faced -- and for many different reasons.

The legislators were caught up in redistricting proposals, the State's budget deficit, raise taxes/cut services arguments, differing philosophies, and the fact that several jurisdictions were hurting a lot worse than others. Add to that the HMOs and the large number of lobbyists working against us on behalf of the HMO industry, and the Maryland Chamber of Commerce, too - and it's a miracle that we got anything passed. The pharmacists of Maryland should be commended for their letters and phone calls need to be recognized. It was of great help to MPhA's efforts and the legislators certainly listened when our members called.

Let me brief you on just a few of the more than 30 bills we tackled this year. A complete listing of the bills worked on by MPhA's Legislative Committee appear in charts following this article.

### House Bills 5/56

Believe it or not, there were a few bills we can categorize as "routine" bills; these included House Bill 5 and House Bill 56. House Bill 5 allowed the Governor to remove a member of a Health Occupations Board, including the Board of Pharmacy, if

that member were absent from more than two meetings without a valid reasons. House Bill 56 was intended to insure that Health Occupations Board members would be prohibited from holding more than two consecutive terms. In addition, both bills also included housekeeping language that clarified how the Boards should operate.

### House Bill 194

House Bill 194 *should* have passed. This bill was designed by the Department of Health and Mental Hygiene to obtain rebates from manufacturers for the Pharmacy Assistance Program. The intent of the bill was to ultimately allow

complete coverage of pharmaceuticals under the program, instead of the limited formulary required by 1991 legislation. It was supported strongly by MPhA and the Department. The bill unanimously passed the House

Environmental Matters Committee and the House of Delegates. When it was referred to the Senate, Senator Larry Young added an amendment in the Senate Finance Committee. The amendment was on behalf of the pharmaceutical manufacturers and would have prohibited the Department from requiring any form of preauthorization for both Pharmacy Assistance and Medical Assistance. This amendment, refused by the House, required that the bill go to a Conference Committee to work out agreement between the House and the Senate. The Senate Conference Committee refused to meet with the House committee members and nothing was resolved. Thus, a valuable and important bill died.

### House Bill 223

A strong lobbying effort by MPhA was launched for the passage of House Bill 223. This bill requires all third-party payors to provide pharmacies with written notice at least 30 days before changes in the rules and requirements of a pharmacy benefits plan. "Timely Notice," as it was called by MPhA, also assures that claims be paid under existing terms for a full 30 days from the date of the written notice. This bill will ultimately help all of the pharmacists trying to keep up with every different plan and their hundreds of changes.

### HB 285 and SB 191

A bill that the House Judiciary Committee defeated was HB 285. This bill, and its companion Senate Bill 191, would have made it a felony to forge a prescription. Organized pharmacy, medicine, and law enforcement turned out in full strength to support the bill. Although the Senate version passed unanimously, their was significant resistance in the House. The House Judiciary Committee, top heavy with lawyers, did not want to make the crime a felony. Their rationale? That it would ultimately cost too much.

## **HB 302 and SB 355**

House Bill 302 and Senate Bill 355 were identical bills that would have required pharmacists to dispense generics for workers compensation cases. The original version of these bills included such awkward demands such as requirements that a special prescription blank be used for workers compensation cases, that the prescription had to have a notation written on it that it was for a workers compensation case, and many more burdensome, unworkable, poorly conceived ideas. Where did this bill come from? The Maryland Chamber of Commerce thought this would be a good idea -- at no time did they ever consult with us about the bill. MPhA has taken the lead among providers in offering the legislature innovative ways to contain health care costs and we were disappointed that the Chamber would attempt to affect pharmacy practice without consulting us first. Fortunately, our opposition to the bill was noted and it was defeated.

## **HB 334 and SB 230**

House Bill 334 and its companion Senate Bill 230 was MPhA's major issue for 1992. This bill was the "Consumer Access/Freedom of Choice" bill that would require all HMOs to allow any willing pharmacy to participate in their prescription drug networks. After strong grassroots effort by pharmacists, the Bill passed the Senate Finance Committee with only one opponent and finally the entire Senate. When the bill was considered in the House Environmental Matters Committee, MPhA's efforts had secured a majority of the votes to pass the bill. Unfortunately, House Environmental Matters Committee Chairman Ron Guns was adamantly opposed to this legislation; he believed it inappropriate to establish a legislative precedent that any Maryland company be required to do business with another. Added to Guns' opposition was that the Speaker of the House, Clay Mitchell, was originally against the bill because of mistaken concerns that it would increase health costs. Speaker Mitchell's pharmacist personally spoke to him about the need for the legislation. Unfortunately, it was too late in the session to correct the damage. Chairman Guns encouraged MPhA and the HMO's association to work out this issue. We will be meeting with their representatives over the summer to try and open all pharmacy networks in Maryland. If networks are not opened, MPhA will be back in the legislature next year, fighting for pharmacists on "consumer access."

## **Senate Bill 151**

Senate Bill 151 - Standards for Counseling Individuals by Pharmacists, is one bill that literally rose from the dead. This bill, mandated by Federal OBRA '90 legislation, requires that pharmacists shall offer to and counsel all Medical Assistance patients and those items that *may* be included in the counseling. It also requires the recording of patient information that you receive from the patient. After proposed amendments by MPhA and the Maryland Association of Chain Drug Stores, the Senate Finance Committee decided that the bill was too much of a headache to deal with and promptly killed it. If the bill had remained dead, more than \$55 million in Federal Medicaid funds for pharmacy programs would have been in jeopardy. Luckily, MPhA has a good enough rapport with that Committee so that we could "gingerly" explain to them that the bill **had** to pass. Later, when they reconsidered the bill, they also added most of the amendments we requested. All this back-and-forth took a great deal of lobbying effort on our part, particularly with the Committee staff.

## **HB 800 HB 1220 SB 504 SB 566**

Several bills in both the House and Senate were aimed at requiring HMOs to pay health care providers their usual and customary rates instead of the current poor reimbursement. These bills (HB 800, SB 504 and SB 566) were all defeated from the strong opposition of the HMO and insurance industry. House Bill 1220, sponsored by Delegate Taylor, Chairman of the Economic Matters Committee, would have allowed pharmacists to collect the difference between usual and customary and the amount paid by a third-party payor directly from the patient. This "balance billing" legislation was defeated in the House Environmental Matters Committee after some arguments regarding Committee assignment of this bill.

## **Senate Bill 655**

Lastly, an important bill for pharmacy as well as other health professionals was Senator Paula Hollinger's Senate Bill 655. This bill provides fiscal independence for all health boards including the Board of Pharmacy. Now, all monies paid by pharmacists for licenses, permits, and other activities will go directly into funding the Board of Pharmacy. In the past, our monies went into the General Fund; if the Board needed additional staff or new equipment, they had to share financial resources with all the other Boards. This bill will be of great help to the profession. ■

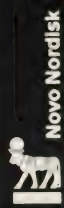
## 1992 Legislation Affecting Pharmacy

### *Bills Introduced in the Maryland House of Delegates*

Bill	Title	Sponsor	Committee	Description	MPhA Position	Final Status
House Bill 5	Health Occupations - Boards	Thomas	Environmental Matters	Allows the Governor to remove a Board member who has been absent for more than 2 Board meetings	Support	Passed
House Bill 56	Health Occupations - Board Membership	Teitlebaum	Environmental Matters	Limits Board members to 2 consecutive terms.	Support	Passed
House Bill 194	Pharmacy Rebate for State Programs	Guns for Department	Environmental Matters	Requires rebates from manufacturers for Medicaid and Pharmacy Assistance	Support	Defeated
House Bill 196	Drug Distributors and Marketing Act	Guns for Department	Environmental Matters	Drug Diversion bill, requires distributors to register with Board of Pharmacy.	Monitor Only	Passed
House Bill 223	Health Care Financing - Payments for Pharmaceutical Benefits Timely Notice	Taylor	Environmental Matters	Requires a minimum of 30 business days notice to pharmacies about changes in third-party program design.	Support	Passed
House Bill 285	CDS Prescriptions - Forgery	Brewster	Judiciary	Changes penalty for forging a prescription to a felony.	Support	Defeated
House Bill 302	Workers Compensation Cases - Generics	Petzold/Littrell	Constitutional and Administrative Law	Requires generics for all workers comp cases.	Oppose	Defeated
House Bill 304	Health Insurance Providers Billing and Reimbursement	Taylor	Economic Matters	Requires health care providers to issue a receipt for services.	Oppose	Defeated

House Bill 334	HMOs - Pharmaceutical Services	Teitlebaum, Weir, LaMotte	Environmental Matters	Requires an open network of pharmacies for HMOs.	Support	Defeated
House Bill 380	HMOs - Liquidation - Priority of Claims	Elliott	Economic Matters	Requires HMOs to pay patients then providers if liquidated.	Support	Defeated
House Bill 384	Pharmacists - Authorization to Substitute Generic Drugs	Guns (Department)	Environmental Matters	Substitutes FDA Orange Book for MD Formulary	Support	Passed
House Bill 537	State Board of Pharmacy	McHale	Environmental Matters	Eliminates residence requirements. Changes MPhA appointment language.	Support and amend	Passed
House Bill 621	Health Insurance Billing for Services	Madden, et al.	Economic Matters	Requires bills to be in simple language, and billing disputes to be resolved by arbitration	Monitor only	Defeated
House Bill 800	HMOs Health Care Providers Payment of Claims	Schisler, Donoghue, Littrell, Hurson	Environmental Matters	Requires HMOs to pay health care providers U/C rates	Support	Defeated
House Bill 1008	Health Care Practitioners - License Revocation	Madden	Environmental Matters	Requires revocation of license if practitioner failed to live up to terms of a federal scholarship.	Oppose	Defeated
House Bill 1220	Health Benefit Plans - Payment for Pharmaceutical Products and Services	Taylor	Environmental Matters	Balance Billing -- Allows a pharmacy to charge the difference between third-party reimbursement and U/C to patient.	Support	Defeated
House Bill 1351	Health Occupations - Boards and Commissions	Guns (Department)	Environmental Matters	Allows Secretary to transfer staff between Boards when necessary. Special funded Boards exempted.	Oppose	Defeated
House Bill 1374	Health Care Cost Containment - Patient Referrals	Guns, LaMotte	Environmental Matters	Prohibits referrals of patients by certain health providers, defines financial interest arrangements, provides exclusions.	Monitor Only	Defeated
House Bill 1378	Health Care Claims Forms	Environmental Matters Committee	Environmental matters	Requires HMOs, third-parties, insurers, to all use a uniform claim form for submission of claims by providers.	Monitor Only	Passed

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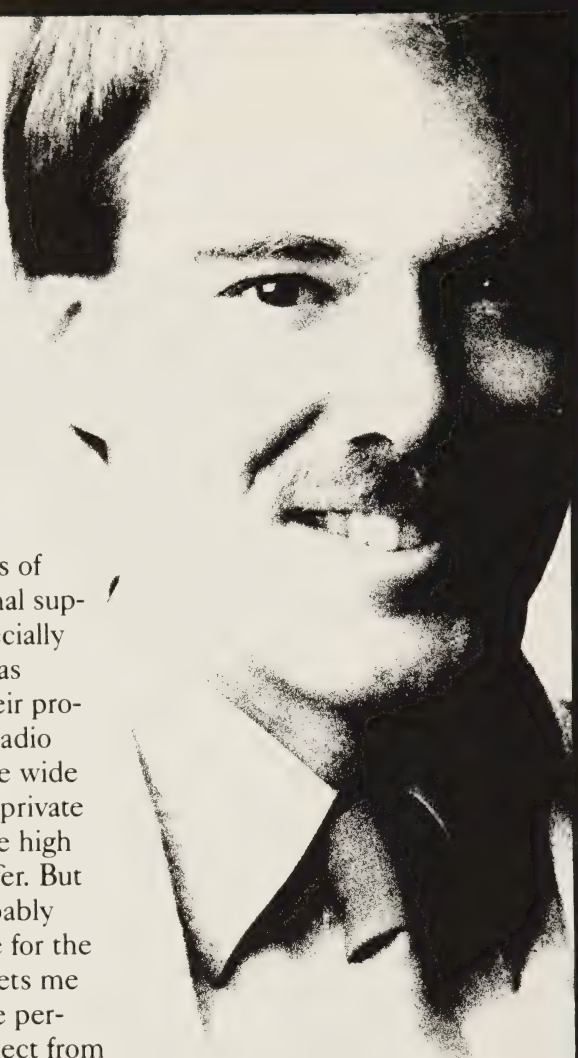
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## 1992 Legislation Affecting Pharmacy

### *Bills Introduced in the Maryland Senate*

Bill	Title	Sponsor	Description	MPhA Position	Final Status
Senate Bill 151	Standards for Counseling Individuals by Pharmacists	O'Reilly	OBRA '90 - Sets up standards for Medicaid patient counseling.	Support and amend	Passed
Senate Bill 191	CDS Prescription Forgeries	Freeman	Makes attempts to pass or forge a CDS prescription a felony.	Support	Defeated
Senate Bill 230	HMOs Pharmaceutical Services	Baker, Young	Requires HMOs to allow all pharmacies to participate in networks.	Support	Defeated
Senate Bill 355	Workers Compensation - Generic Drugs	Derr	Requires pharmacists to dispense generic drugs to workers comp cases.	Oppose	Defeated
Senate Bill 504	HMOs - Health Care Providers - Payment of Claims	Della	Requires HMOs to pay usual and customary charges	Support	Defeated
Senate Bill 566	HMOs - Health Care Providers - Payment of Claims	Della	Sets up definitions of usual and customary charges, requires HMOs to pay U/C.	Support	Defeated
Senate Bill 655	Health Occupations - Fiscal Independence	Hollinger	Allows health boards to become fiscally independent.	Support	Passed



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*Scott Rickards*

**SCOTT RICKARDS**  
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## Pharmacist Salary and Benefits

### A Survey of MPhA Members

*Judith Leister, Pharmacy Student and MPhA PEP Extern*

A survey of the MPhA membership on pharmacist salaries and benefits was mailed to 1,019 members. Of this total, 346 responses were received, representing a 34.0 percent response rate.

The educational background of the pharmacists who responded was as follows: 70 percent obtained their B.S. in pharmacy from the University of Maryland while 30 percent attended various other colleges of pharmacy. Also 16 percent of the respondents held a B.A. or B.S. in another discipline, 8 percent held a Masters or MBA, 3 percent held a Pharm.D., and 1 percent held a Ph.D..

In compiling the responses to the 1992 MPhA Survey of Pharmacists Salary and Benefits, the results have been correlated by the type of practice, position, and sex. Also included is a comparison of salaries based on the number of years in practice.

Salary and benefit breakdown by practice type and sex are shown in the tables 1 on the following pages. Not surprisingly, owners had the highest average salaries for males and females. Male independent owners represented the largest number of survey respondents. The average salary of staff pharmacists in chains and independents was slightly higher for males than females and corresponded to a greater number of hours worked by males. The biggest difference was in the management level positions. Males averaged over \$9,000 more than females in independent settings and over \$11,000 more than females in hospital settings. This difference was not reported in the chain management positions where males and females salaries only differed by \$1,000.

The overall average salary for male pharmacists was 25 percent higher than for females; however most of this difference is related to the significantly higher response rate from the male owners, their higher salaries, and the greater number of hours they work.

Provided benefits varied more by work site than by job position. A lack of relief for lunch and bathroom breaks was the most frequent complaint noted by the chain pharmacists. The benefits reported by owners may be of less value because some owners reported the benefits they receive from the pharmacy while others reported the benefits they provide for their employees.

The average salary by number of years in practice is shown in Table 2. For females the table shows an

#### Average Salary by Years in Practice and Sex

##### Males

Years in Practice	Average Salary	Number	Percent of Total
Less than 1	\$45,233	6	3.0
2 - 5	\$51,358	19	9.4
6 - 10	\$55,752	32	15.8
11 - 15	\$69,096	28	13.8
16 - 20	\$59,717	18	8.9
21 - 25	\$78,022	30	14.8
26 - 30	\$69,186	22	10.8
31 - 35	\$69,209	22	10.8
36 and over	\$61,219	26	12.8

Average Salary: \$64,128  
Total Number: 203 respondents

##### Females

Years in Practice	Average Salary	Number	Percent of Total
Less than 1	\$41,400	10	9.6
2 - 5	\$45,998	34	32.7
6 - 10	\$46,032	25	24.0
11 - 15	\$50,369	16	15.4
16 - 20	\$54,486	7	6.7
21 - 25	\$56,167	6	5.8
26 - 30	\$70,000	1	1.0
31 - 35	\$75,000	1	1.0
36 and over	\$58,700	4	3.8

Average Salary: \$48,393  
Total Number: 104 respondents

#### An Overview of the Results

increase in salary as the number of years in practice increases. For males, however, the salary ranges up and down throughout the years in practice. The one consistency seen in both males and females salaries is as the pharmacists approach retirement (36 years and over) the salaries decrease.

# Compilation of Salary & Benefits Provided to Male Pharmacists By Practice Setting

	Chain Pharmacy			Independent Pharmacy			Hospital Pharmacy			Other Practice Settings			
	Owner	Manager	Staff	Owner	Manager	Staff	Director	Staff	Academe	LTC	HMO	HHC	Other
Overtime	0%	60%	47%	7%	8%	25%	10%	44%	0%	27%	0%	25%	20%
Bonuses	11%	83%	70%	27%	62%	69%	30%	50%	50%	45%	33%	50%	20%
Profit Sharing	11%	40%	27%	16%	38%	31%	0%	6%	0%	36%	33%	75%	30%
Paid Vacations	89%	100%	100%	74%	92%	100%	100%	88%	100%	100%	100%	75%	80%
Sick Days	67%	83%	70%	36%	62%	69%	90%	88%	50%	82%	100%	75%	80%
Personal Leave	78%	43%	40%	30%	31%	31%	90%	75%	50%	82%	17%	50%	50%
Health Insurance	89%	90%	87%	72%	85%	75%	100%	81%	100%	91%	100%	75%	70%
Life Insurance	78%	93%	77%	56%	46%	19%	80%	56%	0%	91%	67%	50%	80%
Disability Ins.	78%	83%	60%	48%	54%	44%	90%	63%	0%	82%	50%	50%	60%
Pension/Retirement	33%	77%	60%	32%	15%	25%	90%	63%	50%	64%	50%	50%	70%
401(k) or IRA	22%	93%	70%	8%	31%	6%	60%	38%	0%	54%	67%	75%	30%
CE Programs	78%	73%	73%	66%	54%	31%	100%	88%	0%	73%	50%	25%	60%
Memberships	89%	63%	17%	44%	38%	25%	50%	6%	0%	82%	50%	25%	20%
Purchase Discounts	78%	23%	53%	66%	92%	100%	30%	38%	0%	91%	17%	50%	40%
Rx Discounts	78%	60%	73%	74%	92%	88%	100%	81%	50%	100%	100%	25%	70%
Lunch and/or Breaks	56%	30%	17%	18%	15%	50%	90%	88%	0%	73%	50%	50%	80%
Child Care	0%	3%	0%	0%	0%	0%	0%	6%	0%	9%	0%	0%	0%
<b>Average Salary</b>	102,240	62,625	50,970	77,230	64,030	49,440	60,900	43,840	61,700	62,200	66,500	54,600	56,700
Hours/Week	52	47	44	52	49	44	44	40	52	44	45	45	43
Average \$/Hour	\$37.81	\$25.62	\$22.28	\$28.56	\$25.13	\$21.61	\$26.62	\$21.07	\$22.82	\$27.18	\$28.42	\$23.33	\$25.36
# Responding	9	30	30	55	13	16	10	16	2	11	6	4	10
Percent of Total	4.2%	14.2%	14.2%	25.9%	6.1%	7.5%	4.7%	7.5%	1.0%	5.2%	2.8%	1.9%	4.7%

Industry -- No data was sent in for male pharmacists.

Compilation of Salary & Benefits Provided to Female Pharmacists By Practice Setting

	Chain Pharmacy			Independent Pharmacy			Hospital Pharmacy		Other Practice Settings				
	Owner	Manager	Staff	Owner	Manager	Staff	Director	Staff	Industry	LTC	HMO	HHC	Other
Overtime	0%	22%	38%	0%	0%	6%	0%	48%	0%	0%	0%	0%	17%
Bonuses	0%	83%	85%	0%	25%	78%	25%	43%	50%	75%	50%	100%	33%
Profit Sharing	0%	56%	31%	0%	25%	7%	0%	0%	0%	50%	0%	0%	17%
Paid Vacations	0%	100%	92%	50%	100%	89%	100%	90%	50%	100%	83%	100%	100%
Sick Days	0%	72%	77%	50%	25%	39%	100%	81%	50%	75%	67%	100%	100%
Personal Leave	0%	44%	46%	0%	25%	28%	75%	71%	50%	50%	33%	0%	50%
Health Insurance	0%	89%	96%	100%	100%	50%	100%	57%	50%	100%	67%	100%	83%
Life Insurance	0%	89%	62%	50%	50%	22%	100%	57%	50%	75%	67%	100%	50%
Disability Ins.	0%	78%	73%	100%	50%	17%	75%	52%	50%	50%	33%	100%	50%
Pension/Retirement	0%	50%	65%	50%	25%	17%	100%	48%	50%	75%	33%	0%	33%
401(k) or IRA	0%	67%	73%	50%	25%	28%	0%	43%	50%	50%	33%	0%	33%
CE Programs	0%	83%	69%	100%	50%	22%	75%	52%	50%	25%	100%	0%	50%
Memberships	0%	17%	27%	100%	25%	6%	25%	0%	50%	75%	50%	0%	33%
Purchase Discounts	0%	44%	58%	100%	75%	78%	25%	10%	0%	75%	33%	100%	17%
Rx Discounts	0%	78%	88%	100%	75%	83%	75%	57%	50%	75%	33%	100%	50%
Lunch and/or Breaks	0%	0%	31%	0%	25%	6%	75%	86%	50%	25%	83%	0%	83%
Child Care	0%	6%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	17%
Average Salary	100,000	56,040	48,020	57,500	47,000	43,530	48,750	43,650	39,600	53,400	51,800	46,000	46,100
Hours/Week	50	43	42	46	42	39	43	41	45	46	40	39	48
Average \$/Hour	\$38.46	\$25.06	\$21.99	\$24.04	\$21.52	\$21.46	\$21.80	\$20.47	\$16.92	\$22.32	\$24.90	\$22.68	\$18.47
# Responding	1	18	26	2	4	18	4	21	2	4	6	1	6
Percent of Total	1.0%	16.0%	23.0%	1.8%	3.5%	16.0%	3.5%	18.6%	1.8%	3.5%	5.3%	1.0%	5.3%

Academe -- No data was sent in for female pharmacists.

## Pharmacists Opinions About Employment and Pharmacy

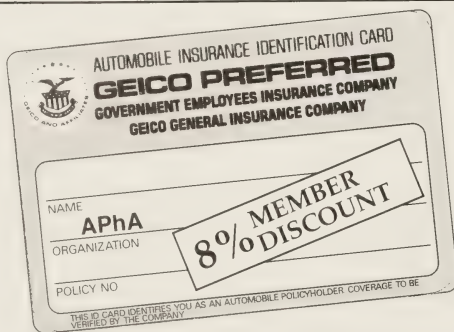
Question	Exc	Good	Fair	Poor	N/A
Physical Working Conditions	33%	50%	14%	2%	1%
Employee/Supervisor Relations	39%	43%	10%	3%	5%
Employee/Employer Relations	35%	50%	9%	2%	4%
Work Atmosphere (Morale)	29%	48%	18%	3%	2%
Practice Site Location	35%	47%	14%	2%	2%
Overall Job Satisfaction	31%	52%	14%	2%	1%
Opportunities for Advancement	13%	23%	24%	31%	9%

Table 3 deals with how pharmacists feel about their job and the profession in general. Pharmacists reported that of all areas the one with the greatest percentage (31%) of poor responses was opportunities for job advancement. Pharmacists were also ask about job changes. 34 percent of the respondents have changed jobs within the last 5 years. They cited reasons such as retirement, better hours, better working conditions, and buying or selling a pharmacy as the main reason for the change. 29 percent of the respondents plan to change jobs within the next 5

years and of those 48 percent plan to take positions outside of pharmacy.

Overall pharmacists seem satisfied with their job. Besides the mention of insufficient break time, the need for scheduled lunch breaks, and the uneasiness about the all Pharm D., the single most cited problem facing pharmacy, especially among the independents, was third party programs.

*Authors Comment:* A special note of thanks to all the pharmacists who took time to fill out my survey and return it.



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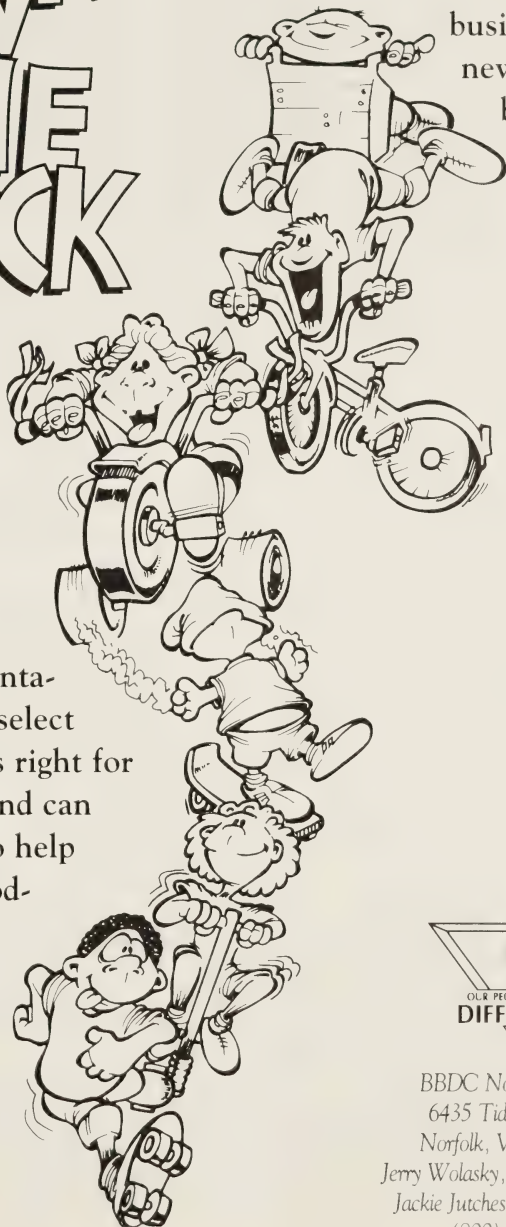
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## Advising Consumers on OTC Hemorrhoidal Remedies: An Update

by J. Richard Wuest, R.Ph.,  
Pharm.D.  
Professor of Clinical Pharmacy  
University of Cincinnati  
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.  
Professor of Pharmacology  
and Toxicology  
Ohio Northern University  
Ada, Ohio

### Goals

The goals of this lesson are to summarize FDA regulations governing OTC hemorrhoidal products, and present important information to assure that consumers use these products correctly.

### Objectives

At the conclusion of this lesson, the successful participant should be able to:

1. demonstrate an understanding of important anatomical structures and



Gossel



Wuest

physiologic events associated with hemorrhoids;

2. select safe and effective ingredients for self-therapy of hemorrhoids;

3. identify OTC hemorrhoidal products and identify pharmacologic and toxicologic actions, warnings and precautions associated with their ingredients; and

4. choose from a list, information for conveying to consumers to assure that self-therapy of hemorrhoids will be maximized.

FDA promulgated its final rule (monograph) in 1990 which defined the conditions under which anorectal drug products are generally recognized as safe and effective for self-therapy. This completed more than a decade of study and intensive review of drugs used to treat these prevalent, yet rarely discussed, conditions. This article summarizes those regulations.

### Background

Anorectal disorders occur in the lower portion of the intestinal tract and interfere with its normal function and/or sensations. The most common disorder is hemorrhoids. Anorectal medications provide relief of discomfort in the perianal area, anal canal and/or lower rectum.

Hemorrhoids are among the most prevalent conditions for which pharmacists are asked to provide advice on product selection. It is reported that one-half of all Americans over age 50 have suffered from hemorrhoids. It is

also estimated that one-third of all households in the U.S. have at least one victim of hemorrhoids.

The exact cause of hemorrhoids has not been determined. They are unique to humans, rarely occurring in other animals. An upright posture is a major contributory factor. Occupations that involve standing for prolonged periods also contribute to their development. Other factors include the relatively low fiber content of the American diet, as compared to other cultures. This leads to harder, less bulky stools. Decreased physical activity lessens the tone of muscles in and around the anus. Pregnancy exerts a significant pressure on the anal region. And overuse (abuse) of stimulant laxatives causes excessive straining of the anal sphincter during bowel movements.

Understanding the anatomy of the rectal area is critical to comprehending what hemorrhoids are, and how drugs act. Sites of concern are the perianal area, anus and rectum.

The **perianal area** consists of skin immediately surrounding the anal sphincter and extending outward in the crease of the buttocks. It contains pain receptors, which makes it unique to the three regions discussed. The anus and rectum have pressure receptors but no nerve endings to sense pain. This is of great importance when considering the usefulness of local anesthetics. Unlike the skin in most areas of the body, perianal tissue is constantly moist and occluded.

The **anus** is the point where external skin changes composition to become the mucous membrane of the rectum. Its major functions are, through cellular composition and sphincters, to guard against entry of foreign substances.

The **anus** has two sphincters: internal and external. The internal sphincter is involuntary and responds to defecation impulses from the autonomic nervous system when stimulated by

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# SEARLE

the pressure of collected residue within the rectum. The external sphincter is under voluntary control.

Anterior to the anus, the **rectum** is the most distal portion of the GI tract. It extends outward for 12-15 cm from the sigmoid area of the large intestine to the anal sphincter. The rectum is lined with mucous membrane and contains pressure receptors that allow the body to perceive the need to evacuate accumulated feces. Its major function is to serve as a collection chamber.

## Hemorrhoids

Hemorrhoids are unusually large conglomerates of blood vessels, supporting tissue, and overlying mucous membranes or skin of the anorectal area. A predisposing factor is that the rectal mucous membrane, like those in other areas of the body, contains a rich vasculature. Veins are most important to this discussion because some drain into the portal circulation which leads directly to the liver, while others drain into the general circulation, by-passing the liver. Drugs absorbed into the peripheral circulation distribute throughout the body without being first metabolized in the liver. Therefore, there is a greater chance for systemic side effects from drugs applied intrarectally.

Veins of the portal system are also important when discussing the cause of hemorrhoids because they do not contain valves, which are present in other veins. They are, therefore, incapable of preventing backflow and pooling of venous blood into the rectal area. Thus, the gravitation of blood resulting from upright stance contributes to its pooling in the hemorrhoidal veins. This increases pressure on the anorectal tissue. When pressure is sufficiently increased, such as during pregnancy and with straining at stool, these blood vessels enlarge. This can cause inflammation of the surrounding tissue and result in hemorrhoids, with itching, burning and pain.

Swelling of hemorrhoids is caused by enlargement of cells in the anorectal tissue due to accumulation of excess fluids in the hemorrhoidal veins. The area can be further enlarged by inflammation caused by trauma of wiping after a bowel movement, or irritation from improperly removed fecal material.

TABLE 1.

### Definitions Relating to OTC Anorectal/Hemorrhoidal Products

- Analgesic, Anesthetic Drug.** A topically (externally) applied drug that relieves pain by depressing cutaneous sensory receptors
- Anorectal Drug.** A drug that is used to relieve symptoms caused by anorectal disorders in the anal canal, perianal area, and/or the lower rectal areas
- Antipruritic Drug.** A topically (externally) applied drug that relieves itching by depressing cutaneous sensory receptors
- Astringent Drug.** A drug that is applied topically (externally) to the skin or mucous membranes for a local and limited protein coagulant effect
- External Use.** Topical application of an anorectal drug product to the skin of the perianal area and/or the skin of the anal canal
- Intrarectal Use.** Topical application of an anorectal drug product to the mucous membrane of the rectum
- Keratolytic Drug.** A drug that causes desquamation (loosening) and debridement or sloughing of the surface cells of the epidermis
- Local Anesthetic Drug.** A drug that produces local disappearance of pain, burning, itching, irritation, and/or discomfort by reversibly blocking nerve conduction when applied to nerve tissue in appropriate concentrations
- Protectant Drug.** A drug that provides a physical barrier, forming a protective coating over skin or mucous membranes
- Vasoconstrictor.** A drug that causes temporary constriction of blood vessels

## Self-Treatable Hemorrhoidal Symptoms

Hemorrhoids that are amenable to self-treatment are mild and self-limiting, and should clear with or without medication. There is nothing available OTC or by prescription to "cure" hemorrhoids. The goal of self-medication is to alleviate symptoms, which FDA describes as burning, discomfort, inflammation, irritation, itching, pain, soreness and/or swelling.

Advanced cases lead to bleeding (over and above minor bleeding that occurs due to wiping), protrusion of a large tissue mass out of the anal sphincter, and inappropriate seepage of feces. These conditions are not self-treatable and require physician supervision. Specific definitions of drugs used to treat hemorrhoids are listed in Table 1.

## Ingredients

FDA differentiates between drugs for external use to the perianal area and those that could be introduced intrarectally. Since pain receptors are located in the perianal area, antipruritic agents, keratolytics and local anesthetics are effective there, but not within the rectum. Some astringents, protectants and vasoconstrictors may provide beneficial effects both externally and intrarectally. Approved ingredients are listed in Table 2.

**Antipruritics.** These are also referred to as analgesics and anesthetics. Some members of this group were originally classified as counterirritants, a term FDA rejected. Most were found to be either unsafe, ineffective or both. Their mechanism of action is felt to be due to stimulation of cold receptors in the perianal area. Since these are higher-level receptors than those for pain, the coolness sensation that results overrides and distracts from the discomfort and itching associated with anorectal/hemorrhoidal disorders.

**Astringents.** When applied to skin or mucous membrane, astringents decrease mucus and other cellular secretions, thereby alleviating local irritation and inflammation. By coagulating surface tissue proteins, they form a thin layer which may protect underlying tissue. Astringents can also aid in removal of surface tissue. They provide temporary relief from burning and itching, but not pain, associated with hemorrhoids.

**Keratolytics.** Keratolytics reduce itching. Their exact mechanism has not yet been determined, but they loosen and induce sloughing of surface cells in the perianal area.

Two keratolytics are approved for use in anorectal/hemorrhoidal products. Alcloxa is thought to act by breaking chemical bonds in the intercellular cement of stratum corneum, thus re-

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TABLE 2.

Safe and Effective OTC  
Anorectal Product Ingredients

## Antipruritics

Camphor	0.1–3%
Juniper tar	1–5%
Menthol	0.1–1%

## Astringents

Calamine	5–25%
Hamamelis water	10–50%
Zinc oxide	5–25%

## Keratolytics

Alcloxa	0.2–2%
Resorcinol	1–3%

## Local anesthetics

Benzocaine	5–20%
Benzyl alcohol	1–4%
Dibucaine	0.25–1%
Dibucaine HCl	0.25–1%
Dyclonine HCl	0.5–1%
Lidocaine	2–5%
Pramoxine HCl	1%
Tetracaine	0.5–1%
Tetracaine HCl	0.5–1%

## Protectants

Aluminum hydroxide gel
Cocoa butter
Cod liver oil
Glycerin
Hard fat
Kaolin
Lanolin
Mineral oil
Petrolatum
Shark liver oil
Topical starch
White petrolatum

## Vasoconstrictors

Ephedrine sulfate	0.1–0.125%
Epinephrine	0.005–0.01%
Epinephrine HCl	0.005–0.01%
Phenylephrine HCl	0.25%

moving dead cells. It may stimulate new cellular growth as well. Resorcinol acts by altering keratin's structure, to increase its pliability and render it more easily removed.

**Local Anesthetics.** Local anesthetics block conduction of pain, burning

and itching sensations to the brain. They are effective for external use on the perianal area, but not for intrarectal application.

**Protectants.** These agents provide a protective covering over skin and mucous membrane, thus preventing tissue irritation. Protectants are approved for both external and intrarectal administration.

**Vasoconstrictors.** These constrict blood vessels. Since one sequelae of hemorrhoids is accumulation of blood in dilated veins, it is felt that vasoconstrictors have a beneficial role when applied to the anorectal area. Additionally, there is evidence that they exert local anesthetic action to alleviate itching.

Ephedrine sulfate and phenylephrine hydrochloride in aqueous solution are safe and effective for both external and intrarectal administration. Epinephrine in aqueous solution is suitable for external use, but will be rapidly inactivated in the alkaline pH within the rectum.

Safe But Unproven Effective  
Ingredients

Two components of anorectal products that were not included in the approved list of ingredients are hydrocortisone and live yeast cell derivatives. FDA continues to evaluate both ingredients.

Live yeast cell derivatives (ingredient in Preparation H and Wyanoids) have been used extensively for many years. It is claimed to be a wound healing agent which accelerates tissue repair to relieve symptoms. During its initial review of anorectal drug products, FDA advised drug manufacturers that two clinical studies demonstrating effectiveness in relief of hemorrhoidal symptoms were needed. Studies were undertaken and results submitted close to the deadline, but FDA did not wish to hold up promulgation of its rule while it reviewed the data. Live yeast cell derivatives-containing products can remain on the market while FDA reviews the data.

Hydrocortisone represents a complex situation because it is under review by a number of different FDA panels, all of which have recommended it for self-therapy. Prescription products containing hydrocortisone are approved for relief of anorectal itching, and OTC external analgesic products

can contain it for the temporary relief of anal itching. However, during FDA's review of anorectal drug products, a hearing was requested to switch hydrocortisone 1 percent to the OTC market, and another to recommend products containing hydrocortisone in combination with a local anesthetic for OTC sale. Since both hearings will take time, FDA did not want to delay promulgation of its rule on anorectal/hemorrhoidal products. So hydrocortisone-containing products, like those containing live yeast cell derivatives, may continue to be marketed and indicated for anal itching.

## Indications

Permissible indications for OTC anorectal drug products are listed in Table 3. Using this table, manufacturers can develop specific indications for labeling their product. For example, the claim "helps relieve the local discomfort and itching associated with piles (hemorrhoids)" meets the monograph's requirements.

Additional indications can be added to the labeling depending on the product's ingredients. For example, products containing local anesthetics can state effectiveness for the symptoms burning, pain and/or soreness. For vasoconstrictors, the terms "temporarily reduces swelling associated with irritated hemorrhoidal tissue and other anorectal disorders" can be used, as well as "temporarily shrinks hemorrhoidal tissue."

For products containing a protectant,

TABLE 3.

Permitted Indications for OTC  
Anorectal Drug Products

- (a) For the temporary relief of  
(b) Gives temporary relief of  
(c) Helps relieve the
- (a) local  
(b) anorectal
- (a) discomfort  
(b) itching
- (a) in the perianal area  
(b) associated with
- (a) hemorrhoids  
(b) anorectal disorders  
(c) inflamed hemorrhoidal tissues  
(d) anorectal inflammation  
(e) hemorrhoidal tissues  
(f) piles (hemorrhoids)

TABLE 4.

**Guide to Hemorrhoidal Therapy  
Based on Approved Indications for OTC Anorectal Drug Products**

	Burning	Discomfort	Irritation	Itching	Pain	Soreness	Swelling
Analgesic, Anesthetic, Antipruritic	Yes	Yes	No	Yes	Yes	Yes	No
Astringent	Yes	Yes	Yes	Yes	No	No	No
Keratolytic	No	Yes	No	Yes	No	No	No
Local anesthetic	Yes	Yes	No	Yes	Yes	Yes	No
Protectant	Yes	Yes	Yes	Yes	No	No	No
Vaso-constrictor	No	Yes	Yes	Yes	No	No	Yes

indications such as "temporarily forms a protective coating over inflamed tissues to help prevent drying of tissue," or "temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful" are allowable. Other allowable claims for these ingredients include "protecting irritated or inflamed areas" and "relieving burning skin irritations or discomfort."

Products containing camphor, menthol or juniper tar can list "for the temporary relief of pain and/or burning," "can help distract from pain" and/or "may provide a cooling sensation." Table 4 summarizes approved indications.

## Warnings

Several warnings must be included on product labels. All must warn that if the condition worsens or does not improve within seven days, to consult a physician. Also, the following must be on the label: the recommended daily dosage should not be exceeded, and in case of bleeding, to consult a physician promptly.

Labels of products intended for external use must warn consumers not to put them into the rectum. For those intended for intrarectal application, the user must be warned not to use the applicator if it causes additional pain when introduced into the rectum. Instead, they should call a physician promptly.

Additional warnings are required for products containing several approved ingredients. Those with a local anesthetic, menthol or resorcinol, must warn: "Certain persons can develop allergic reactions to ingredients in this

product. If the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a doctor."

Products containing resorcinol must warn against use on open wounds near the anus. Those with aluminum hydroxide gel or kaolin must advise consumers to remove any greasy ointment before using the product because they interfere with its ability to adhere properly to the skin.

Products containing a vasoconstrictor must contain the same warnings as required on OTC nasal decongestants, appetite appeasers and bronchodilators: "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor," and, "DRUG INTERACTION PRECAUTION. Do not use this product if you are presently taking a prescription drug for high blood pressure or depression without first consulting your doctor."

None of these effects are of consequence in normal persons, nor are they strict contraindications for patients with the diseases listed in the warning. The concept is that the potential for adverse effects exists, and a physician should decide whether use of the drug is safe, not the patient.

## Counseling Consumers

Pharmacists can play a major role in assisting consumers in selection of OTC hemorrhoidal remedies. A barrier to good communication can occur when consumers are too embarrassed to openly discuss their problem. There-

fore, it is important to listen carefully to what the affected consumer describes in order to recommend the best product.

Consumers should understand that self-treatable hemorrhoidal symptoms should clear in a few days, and that continued self-medication can mask more serious medical conditions. The goal of treatment is to relieve symptoms while healing occurs spontaneously. Self-treatment with OTC products and other measures can help assure increased patient comfort during this period.

Consumers should be advised to wash the anorectal area with mild soap and warm water and to pat (not wipe) the area dry before applying a product. Alternatively, they can use one of the OTC anal cleansing pads such as Tucks or Gentz.

Other ancillary measures that can help alleviate symptoms and occurrence of hemorrhoids include increasing fluid intake and the amount of fiber in the diet. Avoiding straining during defecation is helpful, along with avoiding lifting heavy objects.

Special instructions are necessary to use a rectal applicator (Pile pipe). Consumers should attach the plastic applicator to the open tube, lubricate it well, then gently insert it into the rectum. If it causes pain, they should withdraw it and contact a physician. If there is no pain, they should squeeze the tube to deliver the product, remove the applicator from the rectum, wash it thoroughly in hot soapy water, then replace the cap onto the tube.

Suppositories are no longer considered an efficient means to deliver medication for hemorrhoidal symptoms, but they can remain on the market. If patients prefer their use, they should remove the wrapper before use and moisten the suppository with water. The patient should lie on his/her side and insert the suppository into the rectum slowly, with mild pressure. If the suppository is too soft to insert, it can be held under cold water for a couple minutes or refrigerated for 30 minutes.

As with other OTC products for which FDA has issued its final rule, pharmacists can use the information to properly counsel consumers on their safe and effective use.

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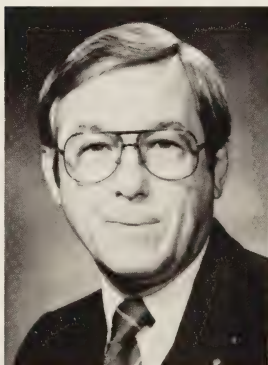


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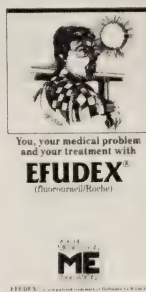
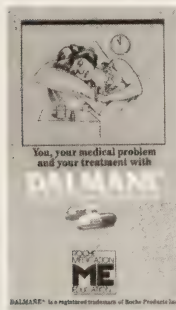
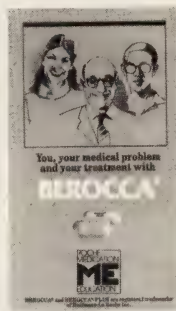
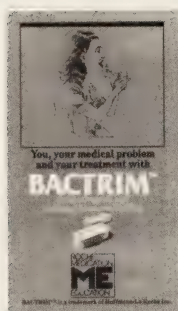


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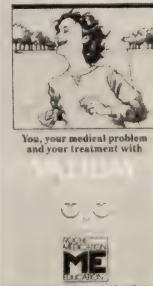
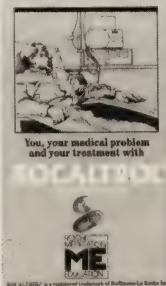
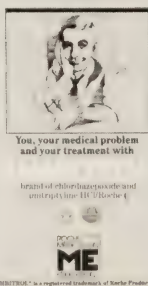
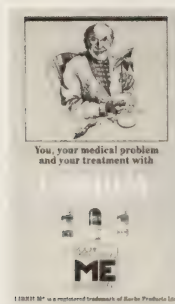


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## Drug Information Questions

### Nicotine Patches

Babette S. Prince, Pharm.D., Roberta L. Brown, Pharm.D.,  
UMAB Drug Information Center

This article provided under a grant-in-aid from **Glaxo**

#### Drug Information Request

What nicotine patches are available on the market? How do they differ? What are the recommended doses?

#### Response

It is estimated that some 50 million Americans regularly smoke cigarettes despite serious health consequences and declining social acceptability. Numerous educational programs, antismoking campaigns, motivational tapes, and medically supervised cessation programs are utilized by smokers who want to "kick the habit."<sup>1</sup> Until now, Nicorette (Marion Merrell Dow) was the only FDA approved pharmacologic agent available to aid with smoking cessation (although drugs such as clonidine have also been used). The FDA has recently approved three transdermal nicotine systems to be used as an aid to smoking cessation for the relief of nicotine withdrawal symptoms. Nicoderm is marketed by Marion Merrell Dow, Habitrol by Ciba-Geigy, and Prostep by Lederle. Another forthcoming nicotine patch not yet on the market is Nicotrol by Warner Lambert.

Nicotine, the pharmacologically active ingredient in cigarettes, binds to acetylcholine receptors at the autonomic ganglia and neuromuscular junctions and to acetylcholine receptors in the adrenal medulla and brain. Nicotine's positive reinforcing properties are believed to be the result of its stimulatory and "reward" effects, and this sets up many people for addiction. The withdrawal symptoms associated with smoking cessation make it very difficult to stop smoking. Craving, nervousness, irritability, moodiness, sleep disturbances, headache, fatigue, and increased appetite characterize the nicotine withdrawal syndrome.<sup>2</sup>

Chronic smoking causes nicotine to accumulate in the body during the day, with nicotine levels diminishing throughout the night. This produces peak and trough nicotine blood levels, arterial nicotine boluses, and decreased early morning nicotine levels. These features lead the smoker to become physically and psychologically dependent upon nicotine in the body. The nicotine patch maintains consistent nicotine blood levels for a full 24 hours. Maintaining steady state nicotine blood levels will

avoid the aforementioned problems which could lead to dependence and withdrawal symptoms.<sup>2</sup>

The transdermal nicotine system uses rate-controlled membrane technology to deliver nicotine for 24 hours. The basic design for the Nicoderm and Habitrol systems is : 1) an occlusive backing, 2) a drug reservoir containing nicotine, 3) a rate controlling membrane, 4) a contact adhesive layer, and 5) a protective liner that covers the adhesive layer that must be removed before application to the skin. Both Nicoderm and Habitrol are available in 21, 14, and 7mg dose patches.<sup>2,3</sup>

The delivery system and dosages are different for Prostep. Prostep consists of: 1) a release liner, 2) a protective foil with well, 3) a nicotine-gel matrix, 4) a backing foil, gelatin and low density polyethylene coating and 5) foam tape and acrylate adhesive. Prostep is available in 22mg and 11mg dose patches.<sup>4</sup>

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#### *Chronic smoking causes nicotine to accumulate in the body during the day*

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Nicoderm is supplied in cartons of fourteen patches. The average wholesale price (AWP) for a carton of 21, 14, and 7 mg Nicoderm patches is \$52.20, \$48.00, and \$44.00 respectively. Habitrol is supplied in thirty patch cartons. The average wholesale prices for 21, 14, and 7 mg patches are \$110.44, \$104.44, and \$99.40 respectively.<sup>2,3</sup> Prostep is supplied in packages of seven patches. The AWP for the 22mg and 11mg patches are \$28.10 and \$25.90 respectively. AWP for a box of Nicorette containing ninety-six pieces of gum is \$32.81 and each box of gum lasts approximately eight days. Upon calculation, the costs of the gum and the patches are about equal.<sup>4</sup>

Before initiating the use of nicotine patches, a medical history needs to be taken. If patients have a history of a recent heart attack, severe or worsening angina pectoris, skin diseases, high blood pressure, peptic ulcer disease, an overactive thyroid, diabetes requiring insulin, kidney disease or liver disease, the use of nicotine patches may worsen these medical problems. Smoking cessation with

or without nicotine replacement, may also alter the pharmacokinetics of certain concomitant medications (i.e. theophylline, leading to a decreased serum half life and increased dose). The patient should be instructed not to smoke while using the nicotine patch because of potential nicotine overdose. Signs of nicotine overdose include headache, dizziness, upset stomach, vomiting diarrhea, cold sweats, and blurred vision.<sup>2</sup> If patients exhibit these symptoms, they should immediately contact their physician.

The dosing of nicotine patches is based on a tapered schedule. It is thought that by tapering the dose of nicotine, the degree of dependence can be gradually decreased. For otherwise healthy patients, initial doses of both Nicoderm and Habitrol are 21 mg/day for four to eight weeks, followed by 14 mg/day for two to four weeks, and finally 7 mg/day for two to four weeks. For patients less than 100 pounds, those smoking less than 10 cigarettes/day or patients with cardiovascular disease, the regimen is slightly modified. The initial dose is 14 mg/day for four to eight weeks followed by a dose of 7 mg/day for two to four weeks.<sup>2,3</sup> Treatment initiation with Prostep is 22mg/day for four to eight weeks followed by an optional weaning dose of 11mg/day for two to four weeks. Again, patients weighing less than 100 pounds should be started on the 11mg/day patch for four to eight weeks with no weaning dose.<sup>5</sup>

In addition to dosing, other important information should be given to the patient. The nicotine patch should be placed on a non-hairy, clean, dry area of the front or back above the waist or the upper outer part of the arm. The patch should not be placed on skin that is burned, cut, or irritated in any way. The patch should be removed from its pouch just prior to use to prevent loss of potency. The hands should be washed after application of the patch because nicotine contact with the eyes and nose can cause stinging and redness. The patch should be applied around the same time each day and rotated to a different site on the skin every day of the week. The patch should not be left on for more than 24 hours. Another important thing to stress is that the nicotine patch should never be cut.<sup>2,3</sup> This alters the rate-controlled membrane such that a steady release of nicotine can not be maintained and the intended therapeutic effect would not be achieved.

The transdermal nicotine system offers an alternative to Nicorette gum. Due to special chewing requirements and

gastrointestinal side effects associated with Nicorette use, many smokers may find the nicotine patch a more favorable choice. Whichever treatment is used however, one must remember that cigarette smoking is a complex addiction with a pharmacologic and behavioral component. Therefore, participation in a formal smoking cessation program while using nicotine replacement therapy should be encouraged.<sup>1</sup>

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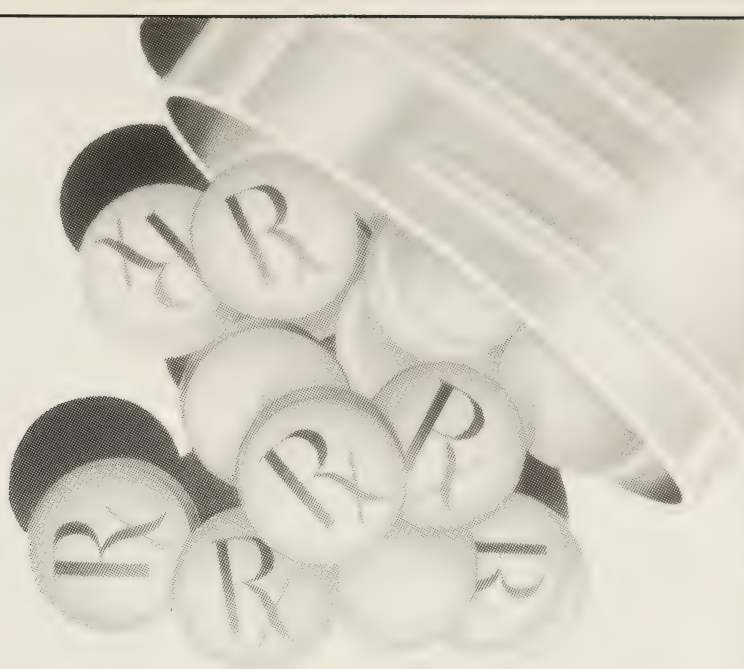
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# Continuing Education

## Continuing Education Quiz

June 1992 -- Hemorrhoidal Remedies

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1. OTC hemorrhoidal remedies containing which of the following ingredients are permitted to make the claim "temporarily shrinks hemorrhoidal tissue?"
  - a. astringents
  - b. keratolytics
  - c. local anesthetics
  - d. vasoconstrictors
2. All of the following are predisposing factors to development of hemorrhoids *excepts*?
  - a. overuse of stimulant laxatives
  - b. decreased physical activity
  - c. a high fiber diet
  - d. occupations that involve standing for prolonged periods.
3. FDA rejected use of which of the following terms as it relates to safe and effective ingredients in OTC hemorrhoidal remedies?
  - a. analgesic
  - b. anesthetic
  - c. antipruritic
  - d. counterirritant
4. Alcloxa is classified as a/an:
  - a. astringent
  - b. keratolytic
  - c. local anesthetic
  - d. vasoconstrictor
5. All of the following ingredients are effective in alleviating symptoms of hemorrhoids when applied both externally and intrarectally *except*:
  - a. astringents
  - b. local anesthetics
  - c. protectants
  - d. vasoconstrictors
6. FDA's definition of a drug that causes desquamation and debridement of surface cells of the epidermis best describes a/an:
  - a. astringent
  - b. keratolytic
  - c. local anesthetic
  - d. vasoconstrictor
7. Which of the following is true?
  - a. hemorrhoids affect most species of animals
  - b. the perianal tissue begins at the anal sphincter and extends inward to the large intestine
  - c. the perianal tissue contains pain receptors but the anal and rectal tissue do not
  - d. resorcinol breaks chemical bonds in intercellular cement of the stratum corneum
8. The warning against using the product if the patient has hypertension, heart disease or thyroid problems must appear on a hemorrhoidal remedy label containing:
  - a. astringents
  - b. keratolytics
  - c. local anesthetics
  - d. vasoconstrictors
9. Which of the following factors is most important to developing hemorrhoids as it relates to the veins in the portal system located in the rectal mucus membranes?
  - a. they do not contain an intimal lining
  - b. there are so few that they are overworked
  - c. they do not contain valves
  - d. they contain pain receptors which aggravate hemorrhoidal irritation

# Classified

**THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION**, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (410) 358-7036.

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# Important figures in diabetes care



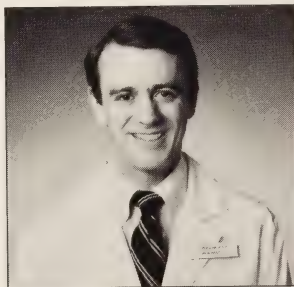
Diabetes is the **No. 7** cause  
of death in the US<sup>1</sup>

---



Diabetes is the **No. 1** cause of new  
blindness in persons aged 20-74<sup>1</sup>

---



Pharmacists see patients with diabetes  
**5** times more often than do physicians.  
These customers spend 3 to 8 times more  
annually in the pharmacy than persons  
without diabetes.<sup>2</sup>

---



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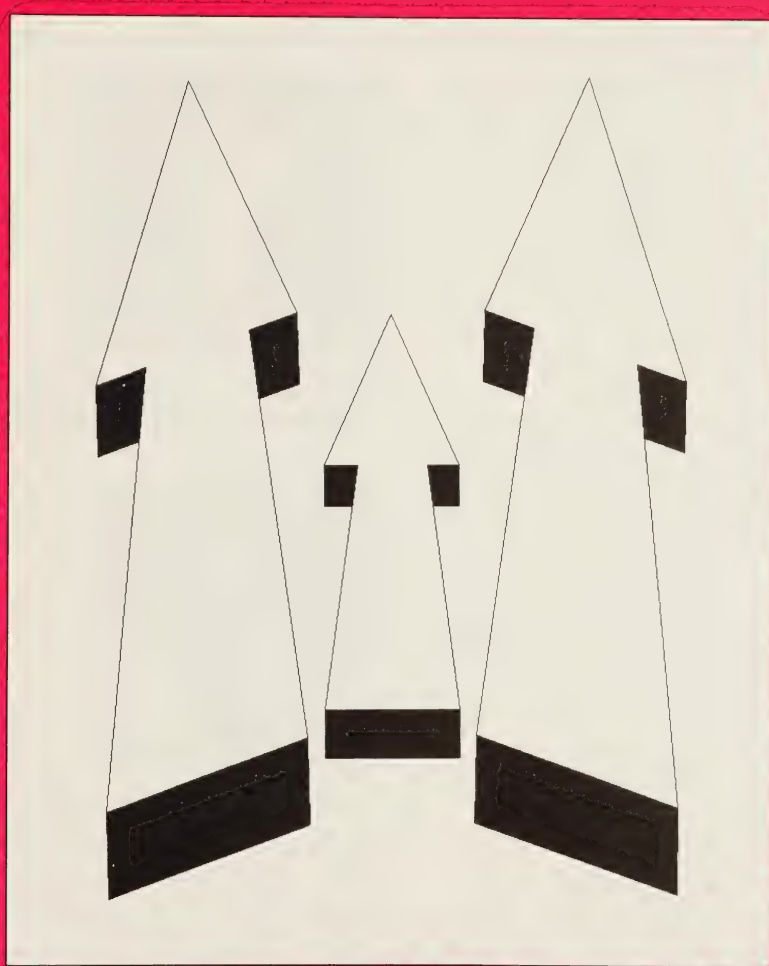
1. *Diabetes Surveillance, 1980-1987*. Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes*. Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

# *The Maryland Pharmacist*

VOL. 68

July, 1992

No. 7



## *Working Together*

Articles from

MSHP, MACDS and the Board of Pharmacy

# Important figures in diabetes care



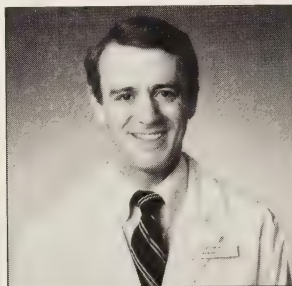
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# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association  
650 West Lombard Street, Baltimore, Maryland 21201-1572

July 1992

Volume 68

Number 7

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## President's Commentary

Nicholas C. Lykos, P.D.

Much of MPhA's educational programming has been devoted to teaching pharmacists how to meet the needs of their patients. Perhaps we need to expand our efforts to include our non-pharmacist pharmacy colleagues as well.

The following letter, sent by me in June to the President of the Johns Hopkins Hospital, clearly illustrates an area that we all need to be aware of - taking care of the *person* as well as the customer/patient. ■

Robert M. Heyssel, M.D., President  
Johns Hopkins Hospital  
600 North Wolf Street  
Baltimore, Maryland 21287

Dear Doctor Heyssel:

At the beginning of the year, I was a patient at your hospital for cardiac surgery by Drs. Bruce Reitz and Levi Watkins.

I felt compelled to write and congratulate your organization for the excellent care provided to me. Everyone at the hospital showed great compassion and warmth during my stay. I must praise the full efforts of your staff and associates -- from the medical, nursing, social services, physical therapy, dietary, food service, housekeeping, and maintenance. All, without exception, were anxious to see that I received comfortable care and were concerned about my needs as an *individual* as well as my needs as a patient.

Frankly, I was amazed that an operations as large and complex as the Johns Hopkins Hospital could provide such consistent attention from its employees.

We in the pharmacy profession are beginning to recognize that our customers and patients are looking and expecting individual care and attention. Our profession must alert and train our employees to respond to the total needs of our patients. We realize that this cannot be accomplished with just employee newsletters or catchy slogans or inspirational posters.

My congratulations and thanks to you and your personnel for creating an environment where every employee recognizes the value of the person.

## Summertime

### *A Season for Pharmacists' Intervention*

*Beverly Yachmetz, Pharm.D., C.D.E.*

Summertime brings a whole new focus to pharmacy practice. Gone are the flus and colds of winter. Coughs and sniffles are replaced with outdoor fun and sun. Summer is a time of vacations and travel. The dispensing of prescriptions often slows down. The role of prevention and self care may drastically increase. The pharmacist is the key person to aid clients in selection of self care items. Such items include over-the-counter medications and first aid products. Pharmacists can educate individuals about the special risk for sun exposure and medications. In addition, travellers benefit from wise advice which anticipate situations which can ruin a well-deserved vacation.

#### "Medicine Cabinet" Inventory

Medicine cabinets (a place which is cool, dry and away from children where medicines and health items are stored) should be stocked with items which fit the needs of the individual household. However, there are some essentials for all homes:

*Syrup of ipecac* Regardless of the household composition, syrup of ipecac is a necessity. The summer brings enticing berries on shrubs which are ingested by children. In addition there are other accidental and intentional ingestions which occur anytime of the year. Remind clients to always contact the local poison control center prior to inducing vomiting. Educational materials on poisonous plants and poison prevention materials are readily available through the poison centers. The Maryland Poison Center number is 1-800-492-2414.

*Thermometer* A fever is a key indicator for a specific course of treatment. Homes with small children or others who are unable to use an oral thermometer should have a rectal thermometer. The "stubby" thermometer is safe for both oral and rectal use. While digital thermometers may be easier to read, battery replacement may be overlooked. Therefore, it may not be operational when needed. The mercury thermometer is always ready for use.

*Antiseptic Skin Cleanser* Minor skin injuries or abrasions generally require only mild soap and warm water to cleanse the affected area. However, for larger areas, non-prescription antiseptics and antibiotic creams are used as skin cleansers and to prevent infection.

Evidence of existing infection requires a referral to a physician.

*Bandages and Supplies* Assorted bandaids and larger sterile pads aid to cover and protect injured skin areas. Sterile pads are secured by mild, hypo-allergenic tape. Band-aids and bandages should be changed frequently and the area assessed by signs of healing or infection. Remember to ask the client about the cause of the wound and assess the need for tetanus protection.

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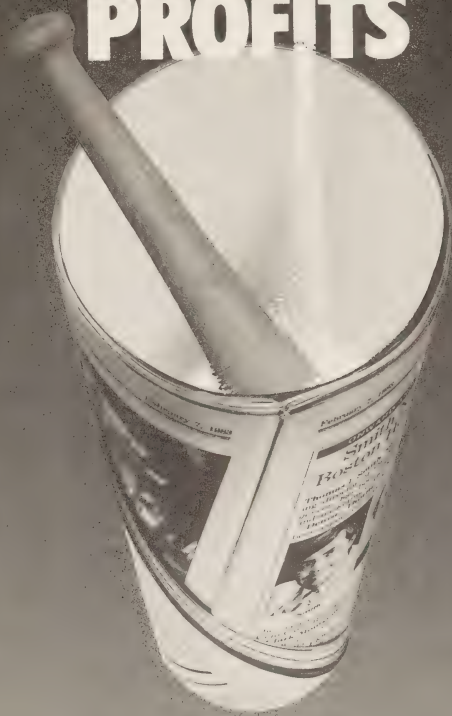
*The pharmacist is the key health care professional to aid in selecting self care items for summer needs*

---

*Pain Relievers* Acetaminophen is the analgesic of choice. This medication has fewer drug interactions and side effects than other available products. The medication should be available in the dosage form necessary for the client such as liquid, tablets or suppositories. In cases where anti-inflammatory properties are needed, ibuprofen is the better choice.

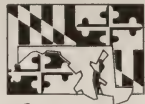
*Other Products* Opinions on other products to stock range to both extremes. Some feel the more products available at home, the better. Others feel that stocking the bare necessities is adequate. Selection of other products should be individualized based on the anticipated needs of the family. Considering other medical problems is helpful in determining additional products to stock, however, unused products result in wasted money. In addition, unnecessary medications may be taken incorrectly due to confusion. Medical conditions and medications may change over time, making some products a dangerous combination. Other standard products which can be considered for stock after evaluation include an antihistamine, an antacid, and a cough medication. Recommendations made should consider the ages of the individuals in the household, other medications used by these individuals, other medical conditions, and the likelihood of use. Remind clients to clean the medicine cabinet annually to discard any expired or deteriorated products.<sup>1</sup>

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## First Aid

First aid is the best first prevention. Pharmacist can alert clients to the hazards of summer. The sun is a particular hazard. Overexposure can cause serious, painful sunburns and blistering. In addition, sun exposure is linked to malignant melanoma and premature aging.<sup>2</sup> Sunblockers vary in efficacy and purpose. The pharmacist assesses the needs of the client and can determine the product most suitable. In addition to the proper sunscreen, clients can be counseled to wear protective clothing such as a hat and a loose fitting long-sleeved shirt. Pharmacists must warn patients taking medications known to cause phototoxic and photo-allergic reactions such as the tetracyclines, the oral hypoglycemic agents, sulfa drugs. These individuals are at particular risk.

Pharmacists can alert individuals to the potential risk of heat exhaustion and heat stroke. Heat exhaustion is characterized by weakness, dizziness, and nausea after physical activity on a hot day. The individual may be dehydrated, but continue to perspire. The treatment consists on removal of heavy clothing, relaxation in a cool environment and fluids, either oral or intravenously.

Heat stroke is a life-threatening elevation in body temperature--usually above 104° F during a high ambient temperature. Heat stroke is classified as either exertional or classical.

Exertional heat stroke occurs most frequently in young, healthy persons who engage in intense physical activity in a hot environment. This places an unreasonable strain on the body's cooling system, and due to a humid environment, the body's ability to release heat through perspiration is diminished. Poor fluid intake also contributes. Individuals with exertional heat stroke are more susceptible to rhabdomyolysis, which can cause kidney injury, and commonly, renal failure.

Classical heat stroke usually occurs in elderly who are debilitated and exposed to hot environments over a long period of time. There is generally little muscle activity involved. Limited cardiac reserve prohibits blood flow to the skin so that the cooling effects can be increased. In addition, perspiration is limited by dehydration and anticholinergic side effects of medications. Classic heat stroke develops slowly, over days. Rhabdomyolysis is less common. These individuals more often experience hypovolemia and cardiogenic shock. Renal injury eventually occurs but failure is less likely, probably due to

the fact that individuals with severe heat stroke generally die.

Again, prevention is the best treatment. Individuals who must be function in hot weather need to limit the activity, dress lightly, stay out of direct sunlight and drink plenty of water or electrolyte solutions. If the person must perform physical activity during the hot, humid days of summer, instruct them to take frequent rest breaks in a cooler environment.<sup>3</sup> Individuals taking antipsychotic medications are at greater risk for the development of heat stroke. Advise your patients of their increased risk and educate them about prevention.<sup>4</sup>

In situations where prevention is not possible, being prepared can minimize the impact of the emergency. Helping clients select proper items for a first aid kit is very helpful. Clients should be encouraged to include first aid items on all vacations and have a first aid kit readily available for home use. Minor injuries or illnesses may ruin a long needed vacation therefore, the vacationers first aid kit may need to be more extensive than home, especially if the trip involves a lot of outdoor activities such as camping or boating.

The pharmacist can advise the client to include the items appearing in Table I.

### *The Complete Summer First Aid Kit*

Band-aids  
Adhesive Tape  
Gauze  
Moleskin  
Scissors  
Thermometer  
Insect repellent  
Sunscreen lotion  
Acetaminophen  
Antibiotic lotion/cream

Table I

Other items such as a bee sting kit, and non-prescription medications (antacid, antihistamine, etc.) may be necessary for individuals who routinely need these products.<sup>5</sup>

Pharmacists can consider other areas to encourage or participate in first aid. The American Red Cross has classes available in first aid which provides training in managing minor injuries. In addition, the pharmacist is taught the basics of wound dressing to assist the patients until physician evaluation can be made. A listing of the classes and schedules can be obtained by contacting the local chapter of the American Red Cross.

Finally, the ultimate in first aid training is completion of Cardio-Pulmonary Resuscitation (CPR). Pharmacist, as health care professionals should be trained and assists in CPR. In addition, pharmacist should encourage clients to be trained in this life-saving procedure.

### Advice to the Traveller

Summer also offers fun and adventure for clients. However, all travelers must be sure to pack health needs. Pharmacists should advise travelers to pack a first aid kit as mentioned earlier. In addition, pharmacists should emphasize the need to carry adequate amounts of prescription medications. Individuals travelling by train or plane should carry the medications on the carry-on baggage rather than the suitcases stored in the baggage compartment. In addition to possible lost luggage, the temperature and storage conditions may be detrimental to drug stability. Medications requiring refrigeration can be stored in a thermos packed with cool, wet newspapers to help maintain the proper temperature. Commercial insulated travelling packs are available for insulin through such companies as Igloo. In addition to medications, pharmacists should advise the travelers to carry adequate supplies or equipment such as strips for blood glucose monitors and a spare battery for meters or hearing aids. Due to varying laws across the states and abroad, an additional written prescription is useful in the event the medication is lost, stolen, or exposed to improper conditions. The traveler should be advised to carry all medications in the original vials for easy identification by custom inspectors.

Individuals travelling abroad or to countries with poor water supplies may need water purification tablets, easily available in the pharmacy. Basic precautions to avoid illnesses include using only bottled water or hot beverages. Individuals should be cautioned about eating unpeeled fruits, raw or undercooked vegetables, meats, fish, shellfish or poultry. In addition, ice cubes should be avoided.

Travelers' diarrhea can ruin the vacation. Vacationers

whose destination is high-risk should contact their physician for advice. Possible treatments include a combination of sulfamethoxazole, 2 trimethoprim, and loperamide for 3 days (160mg. trimethoprim and 800 mg sulfamethoxazole twice a day, along with an initial 4 mg. dose of loperamide followed by 2 mg. after each loose bowel movement, not to exceed 16 mg/day).<sup>5</sup> Prophylactic use is not recommended.

Individuals travelling to areas of high risk for malaria need to seek medical advice prior to departure for appropriate prophylactic treatment. In addition, all individuals travelling out of the United States must be reminded to check all necessary immunizations and health recommendations several weeks prior to departure.

Finally, consider special problems for travelers with chronic disease. Individuals on insulin may need to adjust the insulin dose when travelling by plane and crossing several different time zones. There may be an increase in dose necessary with the increase in time going from east to west, and a decrease in dose necessary when decreasing the day in travelling from the west to the east. Advise your patients with diabetes to specifically ask for directions from the physician. Individuals who must inject insulin while airborne should be instructed to omit the step on injecting air into the insulin bottle.

Individuals with medical conditions which require special dietary considerations should be informed to contact airlines for special diet availability. Finally, all individuals with special diet considerations should carry a food supply along. The individual with diabetes may suffer severe hypoglycemia if the meals are delayed during the flight. By having a supply of fruit, starch, and protein, this individual can avoid the unexpected.

In conclusion, the pharmacist has multiple opportunities during the summer months to provide advice to their clients. The pharmacists can help assure a healthy, happy summer by assessing the risk and providing sound, preventive counseling. ■

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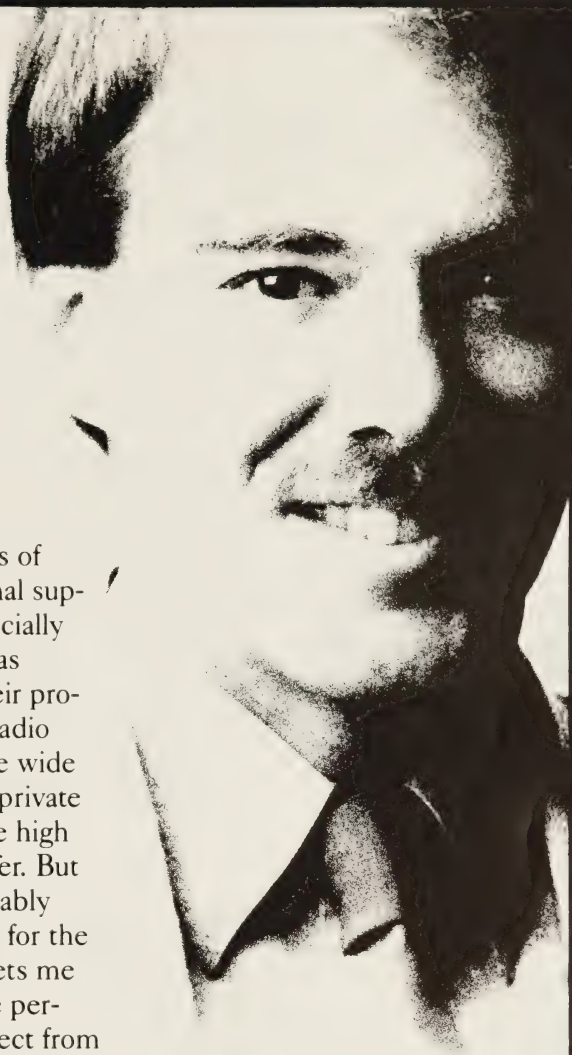
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## Report of the Maryland Board of Pharmacy

*Ralph Small, Secretary, Maryland State Board of Pharmacy*



In compliance with the provisions as set forth in the Health Occupations Article § 12-205 of the Annotated Code of Maryland, this report is submitted to the Honorable William Donald Schaefer, Governor of Maryland, the Secretary of Department of Health and Mental Hygiene, Nelson J. Sabatini and to the Maryland Pharmacists Association.

This is the eighty-ninth report to the Governor and Secretary and seventy-seventh report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the period May 1, 1991 to April 30, 1992. This report is also being submitted to the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records and the State Library.

During the year the Board held seventeen meetings, five of which were held at the School of Pharmacy of the University of Maryland, for the purpose of conducting examinations for licensure of pharmacists.

The Board consists of the following officers and commissioners: Steven S. Cohen, President, Ralph Small, Secretary, William E. Adams, Robert J. Kabik, Dorothy Levi, Theodore S. Litwin, Melvin N. Rubin, and George Voxakis. All of the officers and commissioners are registered pharmacists in the State of Maryland with the exception of Mr. Litwin and Mr. Adams who are consumer (public) members of the Board.

The staff consists of Roslyn Scheer, Executive Director, Brenda Askew, Secretary to the Executive Director and David Oliver, Secretary.

### Examinations

The Board conducted examinations for licensure of pharmacists during the year. They were held at the School of Pharmacy of the University of Maryland on June 25, 26, and 27, 1991 and September 24 and 25, 1991.

The applicants who were examined in June of 1991 were licensed in July, 1991 which is in F.Y. 1992. There were one hundred and thirty-five applicants for the Board in June 1991. One hundred and eighteen passed both the theoretical and practical portions of the examination and were licensed. Seventeen failed the examination.

There were thirty-nine applicants for the Board in September 1991 (F.Y. 1992). Thirty-one passed both the theoretical and practical portions of the examination and were licensed. Eight failed the examination.

Data relative to the June 1992 examination will be given in the next Annual Report.

The pharmacist licensure examination is given in two parts consisting of the following: Part I - NABLEX; Part II consists of Laboratory, Maryland Drug Law, and Federal Drug Law.

The NABPLEX and the Federal Drug Law Exam are obtained from the National Association of Boards of Pharmacy. The Maryland Law Exam and the Laboratory Exam were compiled by members of the Board. The Laboratory Examination requires the compounding of four prescriptions per applicant.

Table I shows the number of pharmacists who were licensed by examination during the past ten years.

<b><i>Initial Pharmacist Licenses Granted</i></b>	
<b>Year</b>	<b>Licenses</b>
1981-1982	100
1982-1983	116
1983-1984	92
1984-1985	92
1985-1986	109
1986-1987	105
1987-1988	121
1988-1989	135
1989-1990	167
1990-1991	156
1991-1992	149

Table I

As in the past, many pharmacists applied for reciprocal licensure in Maryland in order to accept positions with their employers who have stores in Maryland. In all cases, an applicant for reciprocal licensure must appear for a personal interview. The entire Board must act on whether or not to grant licensure to such applicants, who must sign an agreement to comply with Maryland's law pertaining to drugs and pharmacy.

Table II shows the number of pharmacists granted licensure by reciprocity and the number who were certified to be licensed by reciprocity in other states during the past ten years. The table shows Maryland gained 1,022 pharmacists by reciprocity during the past ten years

#### Permits

New permits to operate a pharmacy were issued to sixty-five (65) firms as of April 30, 1992. These permits were issued in the following counties: Anne Arundel - 4; Baltimore - 13; Calvert - 3; Carroll - 1; Cecil - 1; Charles - 2; Frederick - 1; Harford - 3; Howard - 2; Kent - 1; Montgomery - 6; Prince Georges - 9; St. Mary's - 1; Talbot - 2; Washington - 2; Wicomico - 3; and Baltimore City - 11.

Of the sixty-five locations that were issued permits, six were name changes. New permits were issued reflecting the changes.

In June, 1987, regulations were promulgated under COMAR, Title 10, Subtitle 34, Chapter 17, allowing waiver of full service requirements for recognized pharmaceutical specialties. As of April 30, 1992, the

#### ***Pharmacists Granted Reciprocity or Certification***

<b>Fiscal Year</b>	<b>Reciprocity</b>	<b>Certification</b>
1982-1983	103	60
1983-1984	119	58
1984-1985	148	54
1985-1986	191	70
1986-1987	206	75
1987-1988	197	57
1988-1989	228	86
1989-1990	187	103
1990-1991	212	98
1991-1992	178	86
<b>Total</b>	<b>1,769</b>	<b>747</b>

Table II

Board issued twenty-one new pharmacy waiver permits as follows: one in Allegany County, two in Baltimore County, one in Calvert County, one in Carroll County, two in Harford County, four in Howard County, one in Montgomery County, three in Prince Georges County, one in St. Mary's County, two in Talbot County, one in Washington County, and two in Wicomico County.

New permits to manufacture drugs, medicines, toilet articles, dentifrices, or cosmetics as of April 30, 1992 were issued to five firms.

The Board issued twenty-seven new permits to distribute prescription drugs as of April 30, 1992.

The total number of establishments licensed through the State of Maryland is 1,600 and the total number of pharmacists is 7,923 as of April 30, 1992.

#### Legislation

The following bills which affect pharmacy either directly or indirectly were enacted by the 1992 General Assembly. These bills must be signed by the Governor to become effective.

*HB 5 - Health Occupations - Boards - Allows the*



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Baltimore, Maryland 21201-1572

Governor to remove a Board member, including the Board of Pharmacy, who is absent two successive meetings without good reason.

*HB 56* - Health Occupations - Board Membership - Term Limitations - Limits Board members to two consecutive terms and changes the length of a Board of Pharmacy term from five years to four years.

*HB 196* - Maryland Prescription Drug Distributors and Marketing Act - Drug diversion bill authorizes the Board to set standards consistent with the requirements of the U.S. Prescription Drug Marketing Act for wholesalers and distributors.

*HB 384* - Pharmacists - Authorization to Substitute Generically Equivalent Drug Products - Substitutes FDA Orange Book for Maryland Formulary.

*HB 537* - State Board of Pharmacy - Sunset legislation continues the Board of Pharmacy, eliminating city/county residency requirements for Board members and changes the appointments process.

*SB 151* - Standards for Counseling Individuals by Pharmacists - Requires pharmacists to offer to counsel Medicaid patients.

*SB 655* - Health Occupations - Boards - Special Funds - Allows Health Occupation Boards to utilize the funds collected from licensees and allows a degree of autonomy.

### Cooperative Activities

The Board maintained cooperative activities with the Division of Drug Control, Licensing and Certification, the State Department of Health and Mental Hygiene, the University of Maryland - School of Pharmacy, the Maryland Pharmacists Association, the Maryland Society of Consultant Pharmacists, City, County and State Police, the National Association of Boards of Pharmacy, and all Pharmacy Boards and Schools throughout the country.

### Disciplinary Activities

The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. Other complaints were received from the Division of Drug Control, Medical Assistance Compliance Administration, Licensing and Certification, State of Maryland Courts and other state boards of pharmacy.

The wide range of complaints varied in severity. Listed below are statistics concerning the types of complaints for the period of May 1991 through April 1992.

Miscellaneous*	13
Mislabeled prescriptions	4
Incorrect drug dispensed	18
Shortages of controlled drugs	3
Communication	1
Dispensing habits of pharmacist	4
Fraud	1
Professionally, physically, or mentally incompetent	8
Pricing	4
Practice beyond scope permitted by law	2
Freedom on choice	1
Rx not dispensed	2
Negligence	6
Advertisement	1
Theft of drugs	1
Sexual misconduct	1
<b>Total Complaints</b>	<b>70</b>

\*Complaints are on expired prescriptions, advertising, and prescription blanks.

During the period of FY 1992, nineteen Orders were issued and distributed for public information involving eighteen pharmacists and one pharmacy. These appear in Table III.

During this period, the Board voted charges for violation of pharmacy law against twenty-two pharmacists and one pharmacy. Eighteen pharmacist cases and the one pharmacy case have been concluded (included in Table III) and four are still outstanding. Of these, one pharmacist's license is currently suspended on an emergency basis pending final resolution.

The Board has 14 additional outstanding cases from the previous year which have not been concluded.

Some pharmacists were convicted of violating more than one statute. Listed below are the types of violations according to the section of 12-313(b) of the Health Occupations Article and the number of pharmacists charged with each:

- Provides professional services while . . . . . 5
  - (i) Under the influence of alcohol; or
  - (ii) Using any narcotic or controlled dangerous substance, as defined in Article 27 of the Code, or other drug that is in excess of therapeutic amounts or without valid medical indication
- Submits a false statement to collect a fee . . 1
- Willfully makes or files a false report . . . . . 1 or record as part of practicing pharmacy
- Willfully fails to file or record any report . . . 2 that is required by law
- Willfully impedes or obstructs the filing or . . 1 recording of any report that is required by law;
- Without first having received a written or . . 10 oral prescription for the drug from an authorized prescriber, dispenses any drug for which a prescription is required
- Is professionally, physically or mentally . . . . 2 incompetent
- Is convicted of or pleads guilty or nolo . . . . 2 contendere to a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;
- Disciplined by a licensing or disciplinary . . . 1 authority of any other state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes;
- Violates any rule of regulation adopted by . . 2 the Board

Some pharmacies were charged with violating more than one statute. Listed below are the types of violations according to §§ 12-409 and 12-501 of the Health Occupations Article and the number of pharmacies charges for each:

*§ 12-409*

- (1) Is conducted so as to endanger the public health or safety . . . . . 1
- (2) Violates any of the standards specified in 12-403 of this subtitle: or . . . . . 1
- (3) otherwise is not conducted in accordance with the law. . . . . 1

*§ 12-501*

- (1) Whenever a pharmacy is in operation, it shall be constantly under the personal and immediate supervision of a licensed pharmacist. . . . . 1

## Finances

All funds of the Board of Pharmacy are deposited to

<i>Board of Pharmacy Orders Issued</i>	
<u>Pharmacists</u>	
Emergency suspensions	1
Suspensions	2
Suspensions with immediate stay and probation	9
Revocation of license	1
Full reinstatements	4
Revocation with immediate stay and probation	1
<u>Pharmacies</u>	
Fined	1

Table III

the credit of the Treasurer of the State of Maryland and disbursements covering the expenses of the Board are paid by voucher by the State Comptroller.

The Board of Pharmacy had revenues of \$234,580 in 1990 and \$245,735 in 1991. The Board of Pharmacy had expenditures of \$176,662 in 1990 and \$165,624 in 1991. The Board's direct budget is \$187,520 for 1992 with indirect costs of \$205,095.

## Regulations

The Board has the following regulations in progress:

1. Parenteral/Sterile Enteral Compounding;
2. Licensing of Wholesale Prescription Drugs;
3. Fees.

## Continuing Education

Throughout the year the Continuing Education Task Force has accepted requests for approval of Continuing Education (C.E.) programs that are not automatically approved by the C.E. regulations. The second monitoring of C.E. documentation was completed and pharmacists were identified as being non-compliant, resulting in disciplinary action being taken. Preparations are being made for the third monitoring to be processed.

### Secretary/Treasurers Message

As the Senior Pharmacy Board member, I am deeply honored to have been elected to serve as Secretary-Treasurer for the Maryland Board of Pharmacy. When I think back to many distinguished people such as Frank Balassone who have served the citizens of Maryland before me, I have "big shoes" to fill. One responsibility of the Secretary-Treasurer is to deliver an annual report to the Governor and the Maryland Pharmacists Association on the activities of the Board of Pharmacy.

During my previous eight years on the Board, this annual report for me was a "snap". I simply read in *The Maryland Pharmacist* the report as written at first by Paul Freiman and for the past four years by Milton Moskowitz. It was easy to be analytical and critical when someone else did the work. Now, I must follow in my predecessors roles and try to be as thorough as they were.

The pharmacy practice of today is an evolving one that requires planning for the future as we move from a product oriented environment to a profession focusing on pharmaceutical care. This suggests that the pharmacists' role is to help patients make the best use of their medications. What has the Board done, in light of the dynamics of the pharmacy profession, to protect the citizens of Maryland?

Two new members to the Board have been appointed by the Governor, Melvin Rubin and Robert Kabik have moved right in replacing Milton Moskowitz and Leonard DeMino. Both new appointees have immediately assumed important roles in carrying out the workload of the Board. As reported by our previous Secretary-Treasurer, the tough financial condition of the State has not allowed us to employ a full complement of staff, nor to utilize many needed resources. Nevertheless, our Executive Director, Roslyn Scheer, along with Office Staffers Brenda Askew and David Oliver do a commendable job in delivering services to the licensees and the public. Steven Cohen has been re-elected as President, and continues to focus the Board on its missions.

The consumer members of the Board, William Adams and Theodore Litwin, provide inspiration to the Board as they express concerns from a non-pharmacist perspective. The other pharmacists members of the Board, Dorothy Levi and George Voxakis, continue to provide service to the profession that shows dedication and a sense of accomplishment. All the members carry out their duties

with positive results.

As the Board plans for the future, standards of regulation will change. Soon the Board will implement new procedures for the licensing of Wholesalers and Drug Distributors as required by the Prescription Drug Marketing Act. Additionally, Legislation was passed that set standards for counseling by pharmacists.

Furthermore, changes are coming in the role of the health boards within the Health Department. Planning is required to link the short-term with the long-term to insure continuity. Collectively, we will take the lead to position ourselves so that pharmacy can best serve the public.

Because the Board of Pharmacy does not have a staff of drug inspectors, there is heavy reliance on utilization of the inspectors in the Division of Drug Control. Charles Tregoe and his organization work closely with the Board of Pharmacy to ensure compliance with Pharmacy Laws of the State. The Board wishes to congratulate and thank everyone in Drug Control for a job well done.

The Board is committed to serve the citizens of our State. It is a special privilege to be a part of the dynamics of the profession.

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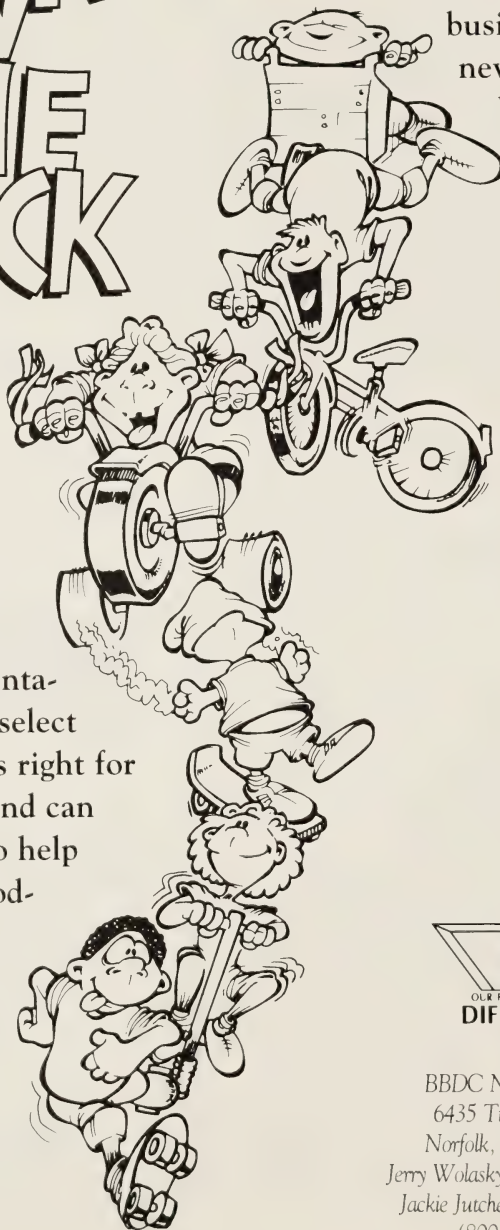
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## History of MSHP -- Part II

*Normand A. Pelissier*

In a request for proposals developed in March 1990 for purposes of soliciting contract vendor support services, the following statement appears: *The membership of the Maryland Society of Hospital Pharmacists can be characterized as having a strong volunteer commitment and traditionally strong supportive leadership.*

Looking back over the Society's activities during the last 10 years, we see ample evidence of this commitment. We also see a lot of dedication, foresight, energy expenditure, teamwork, vision, and purpose. These last 10 years represent a period of tremendous change and growth, both in numbers and professionally. Among the many important issues and activities during this decade were strategic planning; restructuring of the board of directors, the committees and the bylaws; increased involvement with the American Society of Hospital Pharmacists (ASHP), the Maryland Board of Pharmacy, the University of Maryland School of Pharmacy, and the Maryland Pharmacists Association (MPHA); development of a mission statement; a fund-raising art auction; newsletter revision; new MSHP logo; mandatory continuing education; the School's decision to have a single entry-level Pharm.D. degree; contract support services; a Society policy and

procedure manual; many changes in financial reporting and procedures; and institutional pharmacy regulations. Even the hospitals in which most of us work changed.

### Hospital Changes

During this period many hospitals reorganized, merged or otherwise changed their identities. The Johns Hopkins Medical Institutions acquired the Baltimore City Hospitals and renamed this institution the Francis Scott Key Medical Center. Hopkins also acquired the North Charles General Hospital and the Wyman Park Health System. The latter which started out as the U.S. Marine Hospital and later became the U.S. Public Health Service Hospital before becoming Wyman Park Health Systems, was renamed Homewood Hospital Center (Homewood North). North Charles General became Homewood South and a few years later it was closed.

*The membership of the Maryland Society of Hospital Pharmacists can be characterized as having a strong volunteer commitment and traditionally strong supportive leadership.*

Lutheran Hospital and Provident Hospital joined to become the Liberty Medical Center. The Union Memorial Hospital joined with Franklin Square Hospital Center to form the Helix Health System but

each hospital continued to operate independently and retain its separate identity. South Baltimore General Hospital was renamed Harbor Hospital Center and the Baltimore Cancer Research Center moved from the USPHS hospital in Wyman Park to the University of Maryland Hospital. The University of Maryland Medical System (UMMS) was created in 1984 and now includes the Cancer Center, Shock/Trauma Center, University Hospital, the James L. Kerner Hospital, and the Montebello Rehabilitation Hospital.

### Restructuring of the Society

In 1985 the ASHP council on organizational affairs took action to require all affiliated state chapters to amend their constitution and bylaws changing the objectives to be identical with the purposes found in the ASHP charter. The council also requested state chapters to consider amending the current definition for active member to conform with the ASHP definition.

These requests prompted MSHP to restructure its committees and change its bylaws. Some of these changes had already taken place. Beginning with the 1977-1978 year, committees were organized into three categories: Professional Education with Kent Johnson as board coordinator, Membership and Organization with Ray Morris as board coordinator, and Professional Affairs with June Shaw as board coordinator. In 1988 the Society adopted a calendar year business cycle.

The Committee on Resolutions consisting of immediate past and present delegates to the ASHP

*Author's Note* Part I of the MSHP history covered the period from 1944 through 1981 and was published in *The Maryland Pharmacist*, Vol. 57 No. 9 and 10, September and October 1981 issues. Part II covers the 10-year period 1982 through 1991.

House of Delegates was established by the MSHP board in February 1988. Actually, delegates from MSHP began attending ASHP regional delegate conferences beginning in 1975. In 1984, the emphasis and structure of the RDC's changed to discuss and review reports, recommendations, and actions which were to come before the next ASHP House of Delegates session. Along with these changes the Society expanded its board of directors in 1988. The president-elect of the Maryland Pharmacists Association is offered an honorary MSHP board membership. The past MSHP secretary chairs the membership committee and serves a one-year term on the board after completion of one year as secretary. Also, the past treasurer chairs the finance committee and serves a one-year term on the board after completing one year as treasurer.

### Strategic Planning

In January 1987, the Board of Directors established a strategic planning task force to develop both short-range and long-range plans for the Society. The task force first met in February 1987 and another session was conducted by Moe Delcher in early 1988. Later during the year Paul Jeffrey and the strategic planning task force conducted a comprehensive survey examining all aspects of MSHP's purpose and activities. The results of this survey were reported in October 1988. In December 1988, the strategic planning task force issued a strategic planning process which addressed membership definition, the scope of services provided by MSHP, the Society's awards program, the restructuring of committees, the strengthening of legislative and public

affairs efforts, and meeting the new continuing education demands of the State.

In May 1990, the Strategic Planning Committee was approved as a standing committee of the Society "to develop and oversee implementation and fulfillment of the MSHP mission and identify broad goals of the Society". The work of the committee continued through 1990.

The strategic planning committee chaired by Paul Jeffrey also included Becky Finley, Berry Means, Joe Sokol, Janice Dunsavage, Rita Mitsch, and Scott Streater. This committee's primary function was to develop the policy and procedure document for the committee, identify broad goals for the Society, define objectives to meet these goals in support of the MSHP mission statement and to develop a time line for the attainment of the goals.

Several brain-storming sessions were held as ideas were shaped into goal statements with supporting objectives. These objectives included:

1. Redefine the membership of MSHP.
2. Foster an awareness of the role of the pharmacist as an integral member of the health care team.
3. Prepare pharmacy and MSHP for the future.
4. Advocate high standards of professional practice in the delivery of pharmaceutical care.
5. Provide and promote quality educational and training programs to develop and maintain a high level of professional competence for pharmacy personnel.

A follow-up strategic planning survey was conducted in October 1991 by Bonnie Pitt. This included a SWOT (strength, weakness,

opportunity and threat) analysis of MSHP and the profession. The strategic planning process is very important in setting new directions for the Society. The MSHP Mission Statement was developed through this strategic planning process.

### Mission Statement

The Maryland Society of Hospital Pharmacists represents its members affiliated with institutional and other organized health care settings in the State of Maryland. The mission of the organization is to provide leadership in promoting high quality pharmaceutical care in these settings by: 1) Providing opportunities for continuing education and exchange of information for and among its members; 2) Advancing pharmacy as an essential component of the health care team through public and professional awareness efforts; and 3) Promoting the development of properly qualified candidates into the institutional environment. Furthermore, MSHP will actively work to safeguard the integrity of institutional pharmacy practice.

### MSHP Logo

The society's first logo was designed in 1973 by Robert Dawson of the Johns Hopkins University Hospital. It first appeared on the Society's annual seminar brochure in June 1973. In February 1987, a contest was held to update the MSHP logo. The new logo currently used was submitted by

Thomas Turco and was introduced in 1988.

### **Public Affairs**

The first Maryland Pharmacist Week was proclaimed June 17-23, 1990 by Governor William Donald Schaefer. A similar proclamation was made in 1991. This came about because of the work of MSHP's Public Affairs Committee headed by Paul Weidle in conjunction with the Maryland Pharmacists Association. At the first proclamation ceremony held in Annapolis, MSHP was represented by Paul Weidle, Michael Gum, Suzanne Cronquist, and Rita Mitsch.

### **Art Auction**

In April 1987, the MSHP approved joint sponsorship with MPPhA of an art auction/wine and cheese reception fundraiser for the benefit of the pharmacists rehabilitation committee fund. This successful event held in the lobby of the School of Pharmacy raised approximately \$4,500 for the fund and featured approximately 200 pieces by nationally known artists including Andrew Wyeth. The MSHP-MPhA Art Auction Steering Committee included Paul Jeffrey, Dave Perrott, Jan Iwata, Patty Colaizzi, Patty Harwood, and Louise Leach.

### **Newsletter**

Now in its 23rd year of publication, the MSHP Newsletter was first published in October 1969 under the editorship of Norm Pelissier. In 1976, a newsletter revision committee was appointed and co-chaired by Bill Grove and Norm Pelissier. Major changes were adopted at that time. An editor-in-chief position was

established and departmental editors were recruited. After volume 8, The Maryland Hospital Pharmacist was renamed the MSHP Newsletter and a new volume 1, number 1 was published in July 1977 with Bill Grove as editor-in-chief. A continuing education section became a regular feature of the newsletter at that time. In 1991, a contest was held to rename the MSHP Newsletter. The winning entry submitted by Richard Rumrill was Pharmascript and became the official name with the January/February 1992 issue.

### **Board of Pharmacy**

A number of Society members have had the distinction of serving as commissioners on the Maryland Board of Pharmacy. Beginning with Robert Snyder who was appointed in 1975, the list also includes Steven S. Cohen who was first appointed in 1985 and later reappointed in 1990. Mr. Cohen now serves as President of the Board. Dorothy Levi, another hospital pharmacist, also serves on the Board. The Society has worked closely with the Board on many issues. One of these issues concerns development of institutional pharmacy regulations.

### **Institutional Regulations**

The Society first became involved in developing institutional pharmacy regulations in 1968. These efforts were described in detail in part 1 of this history. After numerous hearings and revisions, a meeting was held with the Board of Pharmacy on January 26, 1982. MSHP members in attendance were Bill Grove, Dave Arrington, Pat Birmingham, Peter

Lamy, Tom Patrick, Norm Pelissier, and Bob Snyder. It was reported by Ron Telak in January 1983 that the regulations were still under board review. A hearing was held with the Board of Pharmacy on February 20, 1985 to review the latest draft. In March 1985 the regulations were still under review.

In 1990, a new effort at drafting regulations was begun by Steve Cohen, president of the Board of Pharmacy. Mr. Cohen formed committees to draft regulations for both acute care and long term care facilities. The MSHP institutional pharmacy task force completed its review of Regulations for Institutional Acute Care Pharmacy on May 8, 1991. The Board of Pharmacy draft was reviewed at the August 1, 1991 MSHP Board of Directors meeting and returned with pertinent comments to the Board of Pharmacy where revision is still in process.

### **Awards Program**

The Society presents a number of awards including the W. Arthur Purdum award, the Hospital Pharmacist of the Year award sponsored by Pfizer Laboratories, the MSHP Student Achievement award, the Geigy Achievement award, the MSD President's award and the Squibb Past President's award. The establishment and criteria for these awards were outlined in part 1 of the MSHP history. A recent addition to the awards given by the Society is the MSHP Board of Directors award. First awarded in 1992, the criteria for this award include: a) membership in MSHP for at least 10 years; b) significant, consistent, and on-going contributions to the Society. The

award recipient is chosen by the Board of Directors and receives a plaque and honorary lifetime membership in MSHP. The 1992 award recipient was David A. Knauer.

### **Contract Support Services**

Recognizing the need for a permanent address and office space, the Society obtained temporary space in the Maryland Pharmacists Association headquarters at the Kelly Memorial building in 1986. In April 1991, the Society contracted management services with the Joseph E. Shaner Company, and Carlton Raither of the Shaner Company was appointed director of administrative services. The Shaner Company provides support services to the MSHP including membership and dues processing, newsletter and other mailings, meeting reservations, storage, etc.

### **Membership**

By the end of 1991, MSHP membership had grown to more than 500 paid-up members. Approximately 75% of members were in the active category, 15% were associate members and 10% were student members. In 1962 MSHP had just over 100 members.

### **Policy and Procedures**

In the early 1980s, under the direction of Bill Grove, a policy and procedure for each MSHP office and committee was developed. This manual has been updated several times since and serves as a guide for incoming officers and committee chairmen.

### **Financial Status**

As a result of increased membership and careful budgeting, the Society assets increased to the point where the advice of a financial consultant was obtained for purposes of investing for future needs, both short-term and long-term. From an annual budget of \$27,800 in 1985, six years later the budget had doubled to \$56,300 and was set at \$62,800 for the 1992 year. (Total revenues for 1986 were \$747.00). There were only moderate dues increases during this last 10-year period. Annual dues set at \$25.00 in January 1980 were increased to \$30.00 in January 1986. A new computerized accounting system was implemented which facilitated periodic finance committee audits and allowed easier financial reporting and budgeting.

### **Mandatory Continuing Education**

Mandatory continuing education for relicensure had a positive effect on MSHP meeting attendance and membership. The Maryland Continuing Education bill was signed in 1985 and became effective on July 1, 1986. MSHP monthly meetings began to be approved for ACPE credit in 1990. In addition, the Society has input through the Continuing Education Coordinating Council which includes members from MSHP, MPhA, and the School of Pharmacy. MSHP is an approved provider of continuing education credits based on Maryland Board of Pharmacy regulations.

### **Pharm.D. Program**

The decision by the University of

Maryland School of Pharmacy in 1989 to adopt the single entry-level Pharm.D. degree was not an easy one and did not come about overnight. There was MSHP involvement from the beginning. In September 1986, Dean William J. Kinnard, Jr. met with past and current members of the MSHP board to discuss the Pharm.D. program and conversion to the six-year Pharm.D. entry-level education. The plan was first voted down by the School's faculty in 1987. At that time there were many factors that caused concern. Among these were unclear future manpower needs, an unstable pharmacy reimbursement system, the changing and wide-range roles of the pharmacist, and the financial, faculty and space resources required.

However, this decision was reviewed and approved by the faculty in 1989. Plans for the new program were presented at the February 1990 monthly MSHP meeting. Dean David A. Knapp requested nominations from MSHP to serve on committees for the Doctor of Pharmacy transition process. The following hospital pharmacists' names were submitted. Doctor of Pharmacy Transition Advisory Committee: Patricia Ensor, Paul Jeffrey and Richard Rumrill; Practice Sites Development Committee: Robert Feroli, Gail Rosen and Paul Jeffrey; and External Pharm.D. Committee: David Arrington, Dorothy Levi and Kathrin Kucharski. ■

## Opinions on the All-Pharm.D. Issue

### Results of the Maryland Association of Chain Drug Store Survey

Murhl L. Flowers, P.D., Vice-Chairman, Maryland Association of Chain Drug Stores

In March 1992, the Maryland Association of Chain Drug Stores commissioned Nathan Associates, Inc., to obtain and assess the views and opinions of pharmacists licensed to practice pharmacy in the State of Maryland on education for pharmacy practice.

Mailing labels for all 5,674 actively licensed pharmacists in Maryland were obtained from the Maryland State Board of Pharmacy. Nathan Associates mailed a questionnaire designed to elicit the opinions of pharmacists on education for pharmacy practice to these 5,674 pharmacists. A total of 2,466 pharmacists responded to the survey. This represents more than 43% of all pharmacists actively licensed in Maryland.

I would like to briefly highlight several key findings regarding the views of licensed pharmacists on pharmacy education.

Overall, 61% of the pharmacists indicated that they do not support the Pharm.D. degree as the only entry-level degree. Less than a third (29.4%) indicated they do support the Pharm.D. as the only entry-level degree, and 9.1% stated they are unsure. These results were consistent across all demographic variables including practice settings, year of graduation from pharmacy school, and gender. Significantly, of those pharmacists who are actively practicing in Maryland, 62.3% do not support establishing the Pharm.D. as the only entry-level degree for pharmacy. These results appear in Table I.

It is important to note that among the minority that indicated support for the Pharm.D. degree as the only entry-level degree, more than half (53%) indicated that their support of the Pharm.D. degree is contingent upon current practitioners receiving or being granted Pharm.D. credentials with no further educational requirement. Again, I want to emphasize that 53% indicated their support only if there are no further educational requirements for all pharmacists to receive doctor of pharmacy credentials. Therefore, less than 15% of the survey respondents support the Pharm.D. degree as the only entry-level degree for pharmacy if there are additional education requirements for current B.S. practitioners to obtain Pharm.D. credentials. These findings are depicted in the graph on the following page.

This is important because the Maryland School of Pharmacy has indicated that current practitioners who would like to earn a Pharm.D. degree would be required

#### Support for the Pharm.D. Degree as the only Entry-Level Degree By Pharmacy Practice Specialty

Practice Category	Yes	No	Unsure
Actively Practicing In Maryland (N = 1,403)	28.2%	62.3%	9.5%
Actively Practicing Outside of Maryland (N = 626)	28.9	64.4	6.7
Involve with, but not practicing pharmacy (N = 239)	28.9	64.4	6.7
Not involved with pharmacy (N = 74)	27.0	60.8	12.2
Retired (N = 113)	46.9	40.7	12.4
All Respondents	29.4%	61.5%	9.1%

Table I

to complete 30 academic hours in a program University of Maryland officials estimate would cost between \$6,000 and \$9,000.

When asked to indicate the number of academic years considered to be most appropriate for an entry-level degree in pharmacy, over 72% indicated five or less academic years as most appropriate. Once again, findings were similar for respondents actively practicing in Maryland - 70.5%.

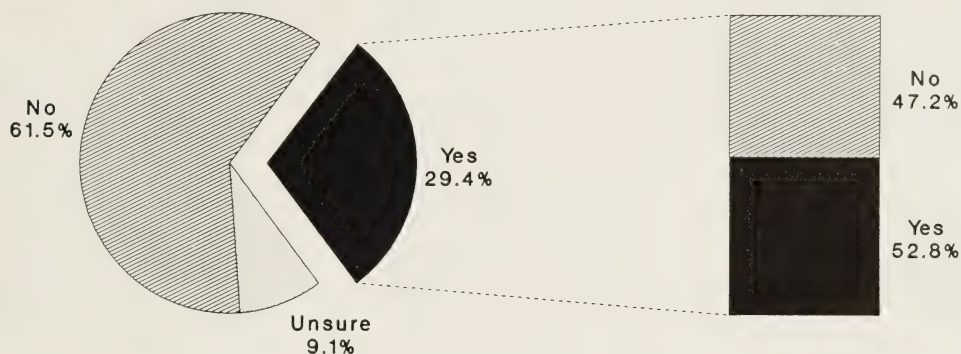
Among the minority of respondents who indicated support for the Pharm.D. degree as the only entry-level

**Support for the Pharm.D. Degree as the only  
Entry-level Degree by Primary Practice  
Setting, Graduation Year, and Gender**

	Support the Pharm.D. as the only entry-level degree			Total	Number of respondents
	Yes	No	Unsure		
-----Percent-----					
Primary Practice Setting					
Hospital/Institution	28.7	60.8	10.5	100.0	708
Independent retail pharmacy	33.5	57.4	9.1	100.0	484
Traditional chain drug store	22.9	68.4	8.7	100.0	520
Supermarket pharmacy	28.5	64.0	7.5	100.0	186
Mass merchandiser	14.3	80.9	4.8	100.0	21
Not currently practicing	38.9	48.8	12.3	100.0	162
Other	31.1	62.5	6.4	100.0	360
Graduation Year					
Pre-1960	32.9	59.9	7.2	100.0	502
1960-1969	33.3	57.9	8.8	100.0	400
1970-1979	30.8	59.6	9.6	100.0	669
1980-Present	24.9	65.6	9.5	100.0	873
All Respondents	29.4	61.5	9.1	100.0	2,460

Support the Pharm.D. as  
the only Entry-level Degree

Support Contingent  
upon Practitioners Receiving  
Pharm.D. without Further Training



degree, nearly one third (30.5%) indicated that five academic years was the most appropriate number of years for an entry-level degree. This indicates another inconsistency between practicing pharmacists' viewpoints and academia's mandatory Pharm.D. proposals, in this case on the length of a Pharm.D. education.

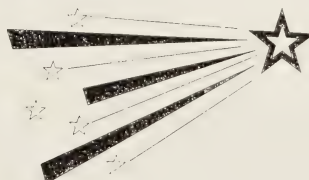
As an additional question, respondents were asked to indicate the degrees they felt should be offered by the nation's schools of pharmacy. Nearly 70% of the respondents indicated that the B.S. degree should continue to be offered. a total of 62.9% felt a Post-B.S. Pharm.D. degree program should be offered, and 56.2% indicated that an entry-level Pharm.D. should be offered. This shows that Maryland Pharmacists feel most strongly about having a B.S. degree program available as an entry-level degree in pharmacy.

In conclusion, the results of this study show that by over a 2:1 margin pharmacy practitioners' do not support establishing the Pharm.D. degree as the only entry-level degree.

The views and opinions expressed by current pharmacy practitioners are of utmost importance and should be

reflected in the educational programs offered by The University of Maryland and the nation's other 74 schools and colleges of pharmacy.

### ***In the August 1992 The Maryland Pharmacist***



**A Full Report from the  
110th Annual MPhA Convention**

# Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

## Correspondence Course

### Update on Sunscreens: Part I

by J. Richard Wuest, R.Ph.,  
Pharm.D.

Professor of Clinical Pharmacy  
University of Cincinnati  
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.  
Professor of Pharmacology  
and Toxicology  
Ohio Northern University  
Ada, Ohio



Gossel



Wuest

1. exhibit an understanding of the various subclassifications of ultraviolet light and whether they tan or burn;
2. identify causes of photosensitivity reactions and the variables that influence sunscreen product efficacy; and
3. distinguish between physical sunblocks and chemical sunscreens and their advantages and disadvantages.

#### Overview of Sunscreens

Many Americans consider tanned skin to be beautiful and healthy. Some have an obsession for sun bathing and spend considerable time in tanning parlors or booths.

During the past several decades, demographic data and direct results of experimentation have uncovered information negating the belief that unlimited exposure to solar rays is healthy. Even short exposures to the sun can harm normal skin. The chronic effects of overexposure are cumulative and persist throughout life.

Recent evidence also implies that ultraviolet A radiation (UVA) is much more devastating than previously believed. Sun exposure is implicated in causing more than 40 dermal and systemic disorders. The most detrimental outcome of prolonged exposure to solar radiation is cellular death.

A wide variety of photoprotection products, which help shield the skin against sun-induced damage, are available OTC. Most sunscreen products are purchased in pharmacies. Since

there is considerable misconception about them, a goal of this lesson is to explain the basis for sun-induced dermal pathology. The lesson also discusses the basis for correct usage of OTC sunprotection products.

Part II of this series will conclude the topic, concentrating on sunscreen products.

#### Solar Spectrum, Tanning and Burning

The solar spectrum of sunlight ranges from 200 to 1800 nanometers (nm). One nanometer is  $10^{-9}$  meter. The higher wavelengths consist of infrared, x-rays, radio and others down to the visible colors. The range that is involved in sunburn and tanning are the lower wavelengths — 200 to 400 nm. These are called ultraviolet, and are further divided into ultraviolet A, B and C (UVA, UVB, and UVC). UVC is 200 to 290 nm, UVB 290 to 320 nm, and UVA 320 to 400 nm.

A common method for labeling these subdivisions is that UVC can cause the most damage and is cytotoxic. It is also called "germicidal" ultraviolet light. UVC can be carcinogenic to human cells, but almost all UVC produced by the sun is filtered out by the ozone layer of the atmosphere.

UVB is more relevant than tanning. Again, most UVB is filtered out by the atmosphere. Also, the goal of traditional sunscreens has been to block UVB from reaching the skin, but allow the UVA tanning rays to get through.

UVA is more responsible for tanning than burning, although it does contribute to sunburn. Briefly, a tan occurs because UVA stimulates melanocytes at the base of the epidermis to produce the pigment melanin. Melanin is the body's mechanism to prevent extensive damage to the dermal layer of skin. Each person has a limit to the amount of pigment that can be formed, and when this is exceeded, sunburn results.

#### Goals

The goals of this lesson are to

1. discuss potential skin damage from ultraviolet (UV) radiation with special reference to UVA rays; and
2. report contemporary information relevant to OTC sunscreen products.

#### Objectives

At the conclusion of this lesson successful participants should be able to:

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# SEARLE

**Table 1****Representative Drug/Chemical Agents that Cause Photoallergic Reactions in Association with UVA**

Group	Compounds	Sources of Exposure
Halogenated salicylanilides and related compounds	Tetrachlorosalicylanilide, dibromosalicylanilide, bithionol, jadit	Antibacterial and antifungal agents in soaps, shampoos, and cosmetics
Phenothiazines	Chlorpromazine, promethazine	Tranquilizers and antihistamines
Fragrances	Musk ambrette, 6-methylcoumarin	Ingredients in after-shave lotions and sunscreens
Sunscreens	PABA and its esters, benzophenones, digalloyl trioleate dibenzoylmethanes	Sunscreening agents
Miscellaneous	Stilbenes, diphenhydramine, thiazides, sulfonamides, sulfonylureas, plants of the compositae family, griseofulvin	Whiteners and brightening agents in bleaches, antihistamines, photochemotherapeutic agents, diuretics and oral hypoglycemic agents

## Sun-Related Damage

Both UVA and UVB cause photosensitivity reactions. As stated earlier, there are approximately 40 sun-related disorders. Those that will be discussed in this article are photosensitivity, photoaging, and skin cancer.

UVB is more harmful than UVA in provoking destructive cutaneous changes. But since most UVB is absorbed by the atmosphere, that which reaches the skin is primarily absorbed in the epidermis.

UVA penetrates more deeply into the dermis and is therefore more likely to promote cellular damage, photoaging, photosensitivity and cancer. UVA is now known to be more potentially harmful than UVB, and is a major risk factor for promoting damage to the skin and its supporting tissues. An important point is that ultraviolet lamps used for tanning emit up to 95 percent UVA radiation and are considered more dangerous than periodic, moderate sunbathing.

## Photosensitivity Reactions

Certain chemicals and drugs that, by themselves, are not injurious to the skin, can incite undesirable photosensitivity reactions when exposed to ultraviolet radiation. The term photosensitivity includes photoallergy and phototoxicity.

**Photoallergy.** Most drug/chemical photosensitivity reactions are provoked by exposure to wavelengths in

the UVA range. The reaction is an immunological response that occurs when a photosensitizing chemical (photoallergen) present in or on the skin absorbs radiant energy and prompts the production of antibodies. Following subsequent exposure to the photoallergen and ultraviolet light, an allergic response occurs. It has been reported that as little as twenty seconds exposure to ultraviolet radiation can initiate a reaction in a sensitized person.

The photoallergic response is more likely to occur with topically applied drugs than with systemic agents. The outcome resembles eczema with discrete eruptions. Edema and vasodilation are common. Lesions may occur within minutes of exposure, or a day later, and extend into non-exposed areas, sometimes covering a large part of the body. Photoallergy occurs less often than phototoxicity. Known photoallergens are listed in Table 1.

**Phototoxicity.** Phototoxicity is more common than photoallergy and involves a non-immunological response to chemicals (Table 2) and ultraviolet light. They can affect anyone. Phototoxic reactions result when an offending chemical is combined with ultraviolet light. An exaggerated sunburn results with a greater than expected reaction for the length of time exposed. Dermal manifestations usually occur 5 to 18 hours after sun exposure and peak 36 to 72 hours later. They may also be delayed for

hours or days. Unlike photoallergy, phototoxic reactions are confined to the site of exposure to ultraviolet light.

Phototoxic reactions can appear following exposure to the sensitizing chemical, either systemically or topically. Some require multiple exposures to produce the response. Following discontinuance of exposure to the chemical or ultraviolet radiation, cutaneous manifestations may persist for months to years. UVA is believed to cause a greater degree of phototoxic reactions than UVB.

## Photoaging

Photoaging broadly describes biochemical and cellular skin changes that occur with continued exposure to sunlight and result in premature aging. UVA radiation is the primary cause. Photoaged skin appears dry and scaly, leathery, yellowish and deeply wrinkled and blotchy.

Photoaging is not merely an acceleration of the normal aging process. Whereas with normal aging the skin becomes thinner because of loss of subcutaneous tissue, photoaged skin thickens due to epidermal hypertrophy. Individuals with fair skin, persons residing in sunny climates, and those exposed to sunlight for extended lengths of time (such as farmers and construction workers) are most susceptible.

Animal studies have demonstrated that UVA is a primary cause of photoaging. Since UVA penetrates more deeply than UVB, it damages underlying connective tissue in the dermis. The photoaging process results from overexposure, so prophylaxis against ultraviolet rays should continue consistently throughout life.

## Skin Cancer

Prolonged or even intermittent exposure to ultraviolet light is reported to be the primary cause of skin cancer, accounting for up to 90 percent of clinical cases. The problem appears to be mediated by UVA, which, on penetrating into the skin, interferes with DNA and RNA synthesis leading to mutated cells which can become malignant.

Individuals at high risk for skin cancer include those with outdoor occupations, fair-skinned Caucasians who easily sunburn, those who live in south-

Table 2

## Representative Drug/Chemical Agents that Cause Phototoxic Reactions in Association with UVA

Group	Compounds	Sources of Exposure
Aminobenzoic acid (PABA) and derivatives	PABA, glyceryl PABA, amyl dimethylaminobenzoate	Sunscreens, UV-cured inks
Benzofurans	Amiodarone	Antiarrhythmic therapy
Coal tar	Anthracene, acridine, fluoranthene, pyrene, benzpyrene	Psoriasis and eczema therapy
Furocoumarins	Psoralen, 5-methoxypsoralen, 8-methoxypsoralen	Photochemotherapy, perfumes, plants
Hypericum (St. John's wort, buckwheat)	Hypericin	Cattle feed, herbal medicines
Nalidixic acid	Nalidixic acid	Urinary antiseptic
Nonsteroidal anti-inflammatory drugs	Piroxicam	Anti-inflammatory agent
Penicillium compounds	Griseofulvin	Antifungal therapy
Phenothiazines	Chlorpromazine, thioridazine, promethazine	Tranquilizers, antihistamines, insecticides, antinematode agents
Retinoids	Etretinate, isotretinoid, tretinoid	Acne and psoriasis therapy
Sulfonamides	Sulfanilamide, sulfacetamide, sulfadiazine, and others	Antimicrobial therapy
Tetracyclines	Demeclocycline, methacycline, oxytetracycline, doxycycline, tetracycline	Antibiotics
Thiazides and related drugs	Chlorothiazide, hydrochlorothiazide, furosemide	Diuretics

ern climates, persons with numerous unusual moles, and those genetically predisposed such as albinos.

The three most prevalent forms of skin cancer are basal cell carcinoma, squamous cell carcinoma and malignant melanoma. The first two are more prevalent (as many as 400,000 and 100,000 victims affected annually) than the latter, in which only 25,000 to 28,000 persons are affected yearly. However, malignant melanoma is the most serious form. If it is undiagnosed and untreated, it can penetrate deeply into the skin and metastasize to other areas of the body.

**Malignant melanoma** begins as a light brown to a black, flat, sometimes mottled blemish with irregular borders. The initial lesion is usually about one-fourth inch in diameter which then expands in size. It can change colors with bright blue and red being

reported, and may crust on the surface and bleed. The most common sites of occurrence are the trunk, upper back, lower legs, neck and head. Deaths from this serious form of skin cancer are increasing at a rate of 4 percent a year. More than 6,000 Americans die of melanoma annually.

**Basal cell carcinoma** (the type President Reagan had) begins as raised opaque, pearl-colored nodules. These neoplasms grow slowly and can invade the underlying structures. However, they do not spread to other organs. Left untreated, these cancers can crust, form ulcers and bleed. The most common sites of occurrence are the face, neck, head, hands and trunk of the body.

**Squamous cell carcinoma** lesions begin as raised pink to red, translucent nodules that occasionally appear like warts. As they grow they sometimes

develop into large tumors that resemble mushrooms. More advanced tumors ulcerate and bleed. The most common site for occurrence is the face, lips, ears, hands and arms.

Detected early, surgical removal of thin melanomas will cure most affected persons. With basal cell and squamous cell carcinomas, early detection and removal reportedly cures 95 percent of all cases. This points out the need and advisability of constant observation for the beginning of these lesions in highly susceptible persons.

## Sunblocks and Sunscreens

In addition to completely avoiding the sun or wearing protective clothing when outdoors, applying sunscreens or sunblocks can prevent ultraviolet light from reaching the skin.

**Physical Sunblocks.** These are chemicals which, because of their opaqueness, reflect and scatter up to 99 percent of light in both the ultraviolet and visible spectrums. Physical sunblocks include red petrolatum, titanium dioxide, and zinc oxide. They are ideal for use on localized sun-sensitive areas, such as the nose, lips, and ears to augment chemical sunscreen agents. Their effectiveness depends on the thickness of application.

Sunblocks are messy to use and generally cosmetically unacceptable for application over large areas of the body. The current fad is to color them with bright fluorescent shades.

**Chemical Sunscreens.** FDA considers sunscreens to be drugs, rather than cosmetics, because "they are intended to protect the structure and function of the human integument (skin) against actinic (sun-induced) damage."

Chemical sunscreens differ from sunblocks in their mechanism of action. Sunscreens absorb various wavelengths of light and thus keep them from penetrating into the skin. A sunscreen's **absorbance** defines the specific wavelengths that are absorbed. **Transmission** refers to the wavelengths that are not absorbed, but pass through the sunscreen layer to underlying skin.

Sunscreens are subdivided into two groups: those that mainly absorb UVB, and those that primarily absorb UVA. It has long been known that most sunscreens provide little protection against UVA.

Aminobenzoic acid and its esters, the cinnamates, and the salicylates primarily absorb UVB. The benzophenones and anthranalates confer partial protection against UVA damage. Butyl methoxydibenzoyl methane protects against the entire UVA range. Sunscreen products that filter out both UVB and UVA are termed full-spectrum or broad-spectrum sunscreens. A combination of two or more sunscreens is often used in products to extend protection over a greater range of ultraviolet radiation wavelengths.

There are many reasons to support using a full-spectrum sunscreen. Foremost is that UVA-induced photo-damage is cumulative. Further, outdoor lifestyles, use of tanning parlors, the natural tendency to prolong exposure to UVB because of the use of high SPF-value sunscreens, and wide use of photosensitizing drugs and chemicals that cause reactions when combined with UVA radiation are all reasons to maximize protection against sun radiation with full-spectrum sunscreens.

## Susceptible Skin Types

FDA has identified six skin types based on genetically determined responses to sunlight. These range from very fair (Type I) to heavily pigmented (Type VI) skin. The need for photoprotection correlates with these skin types. Individuals with fair skin and blue eyes, with or without freckles, who burn easily and tan poorly (Types I and II) should use a sunscreen with an SPF of 15. People who burn moderately or minimally and tan well (Types III and IV) should use a product with an SPF of 6 to 10. Those who rarely or never burn (Types V and VI) require minimal protection and can select a product with an SPF of 2 or 4, or use none at all.

## Sun Protection Factor

The sun protection factor (SPF) is the standard means to express sunscreen efficacy. It is the ratio of the minimal erythema (redness)-causing dose (MED) of UVB (or the minimal amount of UVB that produces uniform redness 24 hours after exposure of sunscreen-protected skin) to the MED of unprotected skin. SPF quantifies the degree of erythema reduction conferred by a particular sunscreen.

Expressed practically, the SPF value is the relative length of time (NOT

HOURS!) an individual can be exposed to UVB when a sunscreen is applied, compared to when it is not used. An SPF value of 15 means that a person can be exposed to UVB 15 times longer with sunscreen protection than without it. SPF values aid consumers in choosing the ideal product for their personal use.

Several products claim to have SPF values higher than 15. An SPF 15 sunscreen absorbs more than 93 percent of UVB radiation. FDA is investigating whether products with higher SPF numbers have improved value over those with the 15 value.

## Phototoxic Protection Factor (PPF)

Currently there is no standardized method for describing sunscreen protection activity against UVA. The phototoxic protection factor (PPF) is one reference which may be of value for this purpose. It is gaining considerable support.

PPF values indicate a sunscreen's UVA-blocking efficacy. The value is obtained similarly as the SPF, with one exception. A delayed erythema is induced by calculating the minimal phototoxic dose (MPD) of UVA radiation in association with a topical or oral phototoxic drug such as 8-methoxypsoralin. The MPD is the minimal quantity of UVA that will induce a uniform redness after exposure to sunlight. The clinical significance of the PPF value is that persons who take or use photosensitizing drugs listed in Tables 1 and 2 and those concerned about photoaging, skin cancer, and other photodermatoses, could use this scale to select their sunscreen because they are especially sensitive to UVA radiation.

There is some controversy associated with the measurement of photoprotection against UVA. The PPF ratio described above was submitted to FDA by Herbert Laboratories, manufacturer of Photoplex, via the new drug application (NDA) process. Therefore, FDA has reviewed and approved this designation, and will permit Herbert Laboratories to make claims about Photoplex protecting against UVA, and being a broad-spectrum sunscreen.

Other manufacturers are making similar claims, however, and one has provided FDA with data distinguishing the damaging effects of subunits of

UVA. That manufacturer claims that the 340-400 nm UVA wavelengths cause a different degree of damage than the 320-340 wavelengths. It has subdivided UVA into UVA I for the former, and UVA II for the latter, and has devised a "UVA protection percent number."

In a feedback letter to the industry in May, 1990, FDA objected to "broad-spectrum" claims for sunscreens (except for Photoplex, which has an approved NDA) on the basis that a testing standard has not yet been adopted to support claims for both UVA and UVB protection, unless, of course, the manufacturer has filed a new drug application — the process Herbert Laboratories followed.

In another interesting announcement, FDA stated that it expected to address UVA in the Tentative Final Monograph for OTC sunscreens due to be published in late 1990, but not to the extent and scope that industry expected. This is because there has been an extended time lag in the OTC review process. FDA is now commenting on a review of marketing conditions up to 1975, and data that have come to light since then will not be acted on for at least another two years.

## Part II

This lesson will be continued with Part II. Topics include a discussion of specific sunscreen agents and OTC sunscreen products with special reference to blocking UVA, and counseling advice for consumers.



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# DRUG PRODUCT QUALITY Review

A PUBLICATION OF THE USP DRUG PRODUCT  
PROBLEM REPORTING PROGRAM

No. 21

## THE RIGHT CHOICE

Questions have been received through the USP Drug Product Problem Reporting Program (DPPR) asking the difference between a product that bears the "USP" designation on its label and a product that does not. Pharmacists wonder whether the presence or absence of the "USP" designation is any indication of differing product quality.

...

### USP REVIEW

As pharmacists are aware, the United States Pharmacopeia (USP) sets the public standards for the strength, quality, purity, packaging, and labeling of drug products available in the United States. If a *USP* monograph exists for a drug product, the drug product is subject to the USP standards set for it. This is required by the Federal Food, Drug and Cosmetic (FD&C) Act and by various state laws as well. This is true whether or not the article bears the initials "USP" on the label.

When a product label bears the "USP" designation, it simply is an express representation that a product does meet USP standards. In addition to USP standards, the specifications contained in the NDA/ANDA for a drug product (private standards) also apply. If a drug product differs from existing USP standards of strength, quality, or purity, the product label must state "Not USP" and plainly state its difference from the official product.

For drug products where no monograph exists in the *USP* or its *Supplements*, the product must only meet the criteria set forth in its NDA/ANDA. "Old drugs" that are not in the *USP*, and do not hold an NDA/ANDA, need only meet their labeled criteria. For example, if a product is labeled as "Sterile Nose Drops," the product must be sterile.

It is also worth noting that some official dosage forms are not regulated as drug products. As previous *Reviews* have pointed out, certain official vitamin/mineral products are regulated as foods. Therefore, USP standards may be enforced differently by the Food and Drug Administration (FDA). However, any product that bears "USP" on its label, whether regulated by the FDA as a food, drug, or even a medical device or cosmetic, must meet USP standards.

The standards set forth in the *USP* are applicable not only at the time of manufacture, but throughout the product's shelf-life. Patients have the right to expect that the medication dispensed to them complies with applicable legal requirements. In selecting drug products, pharmacists are urged to check the *USP* and its *Supplements* or the *USP DI* to see if a monograph exists. If so, all products in the marketplace bearing the same generic name as the monograph should meet the requirements set forth therein. If there is ever any question about whether a particular drug product meets pharmacopeial standards, USP recommends that pharmacists obtain assurance from the manufacturer that its product does, in fact, meet compendial standards.

To report problems with drug products, or for further information, call the USP DPPR Program at 1-800-638-6725.

## Continuing Education Quiz

July 1992 -- Sunscreens, Part I

Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by January 31, 1993. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

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Is this program used to meet your mandatory CE requirements?

☐ Yes ☐ No

Was this issue/article useful to you in your practice?

☐ Yes ☐ No

1. The form of ultraviolet light that is referred to as "germicidal" is:
  - a. UVA
  - b. UVB
  - c. UVC
2. All of the following statements about photoallergy are true *except*:
  - a. it is an immune response
  - b. it prompts the production of antibodies
  - c. it is more prevalent than phototoxicity
  - d. it occurs more often with topically applied drugs than with systemic drugs
3. The type of ultraviolet light-induced skin disorder that most resembles eczema, with discrete eruptions and local edema and vasodilation, sometimes covering a large part of the body is:
  - a. photoaging
  - b. photoallergy
  - c. phototoxicity
  - d. skin cancer
4. The subdivision of ultraviolet light that is more responsible for tanning than burning is:
  - a. UVA
  - b. UVB
  - c. UVC
5. All of the following are physical sunblocks *except*:
  - a. padimate O
  - b. red petrolatum
  - c. titanium dioxide
  - d. zinc oxide
6. Each of the following terms and definitions is correct *except*:
  - a. absorbancy defines the specific wavelengths of ultraviolet light that a sunscreen absorbs.
  - b. PPF values indicate the UVA blocking efficacy of a sunscreen.
  - c. transmission defines the wavelengths of ultraviolet light that pass through a sunscreen and reach the skin.
  - d. SPF values indicate the number of hours that the user can stay in the sun without burning.
7. The wavelength spectrum for the UVB portion of ultraviolet light in nanometers is:
  - a. 200-290
  - b. 290-320
  - c. 320-400
  - d. 400-430
8. All of the following statements about phototoxicity are true *except*:
  - a. it results when an offending chemical is combined with ultraviolet light.
  - b. it resembles an exaggerated sunburn.
  - c. it is believed to be more likely caused by UVA than by UVB
  - d. it occurs on both exposed and non-exposed areas of the body.
9. The type of skin cancer that occurs most commonly, and is characterized by raised, opaque, pearl colored nodules is:
  - a. basal cell carcinoma
  - b. malignant melanoma
  - c. squamous cell carcinoma

# Classified

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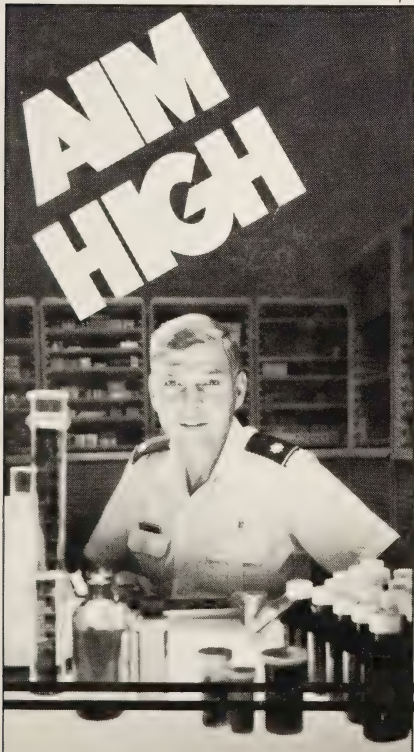
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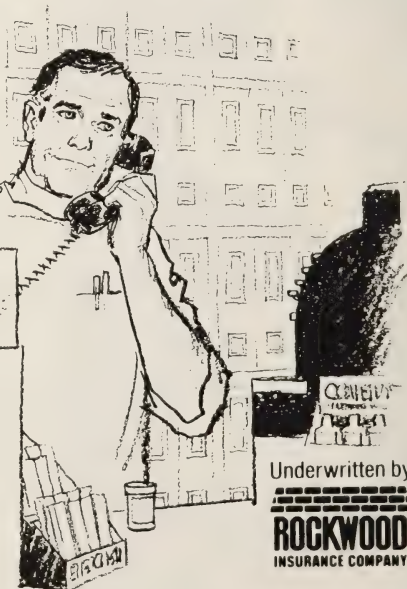
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# *The Maryland Pharmacist*

VOL. 68

AUGUST, 1992

No. 8



*Soaring to New Heights*  
Reports from the 110th Annual Convention



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# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association

650 West Lombard Street, Baltimore, Maryland 21201-1572

August 1992

Volume 68

Number 8

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# Commentary

## President's Commentary

Nicholas C. Lykos, P.D.



The dictionary defines "convention" as the "act of coming together." During the week of June 14 through 17, pharmacists from around the state left their practices for a few days and came together in Ocean City for the 110th Annual Convention of the Maryland Pharmacists Association.

The MPhA Annual Convention is more than just another pharmacy meeting. It's more than just another way to earn continuing education credits.

Our Convention is where our members can share their thoughts and experiences with their fellow practitioners. This is where the Association reports on its status to the membership.

Here at the convention the organization is recharged. There is a "changing of the guard" with the installation of newly elected officers and trustees. New directions for the Association are dictated through various resolutions and open, frank debates during the business sessions.

The Convention is the place where our vendors and supporters come together with us to show, display and demonstrate new products and services for our practices. In a relaxed, stress-free environment, pharmacists can freely talk with the industry, resolve problems, and obtain assistance for special needs. It also allows the opportunity for vendors to canvass many eager pharmacists in a concentrated setting. This dialogue is mutually beneficial for the pharmacist and the exhibitor.

The Convention affords for each pharmacist the opportunity to further their expertise by participating in continuing education credits.

Also, last but not least, the Convention allows pharmacists to relax in a vacation atmosphere. The Association plans very well the integration of work and pleasure. There is time for sun and beach, exhibitions of vendors, crabs and beer, sun and beach, ice cream parties, continuing education seminars, sun and beach, cocktail parties, resort activities, and more sun and beach.

This issue of *The Maryland Pharmacist* contains reports given at the 110th Annual Convention, resolutions debated and adopted by the House of Delegates, and an overview of some of the accomplishments made by your organization. If you missed this year's affair, plan now to join your colleagues in June 1993 at the 111th Annual MPhA Convention. ■

## The State of the Association Report

*Ilene H. Zuckerman, Pharm.D., 1991-1992 MPhA President*



Last year, when I took this office, I told you about my dedication to the successful future of the pharmacy profession; I told you that I was particularly dedicated because my five year old daughter wanted to become a pharmacist. Well, she's six years old now, and she has changed her mind; her new career goal is to work at a fast-food restaurant. I want to assure you, in case there were any doubts, that my commitment to pharmacy has not diminished.

Many of the major accomplishments of the Association are included in the Committee reports. I urge you to review them closely as they will give you a keen perspective on just how much the organization does for pharmacy.

Well, we have accomplished a lot of little things this year, and a lot of big things. Let me tell you about some of them. I'll let you decide which of these are "little" and which are "big."

It always bugged me that MPhA members received their monthly journals a month late. I don't know -- perhaps I'm the only one that noticed this. Over the past year, we played "catch-up" with the magazine, and hopefully you've noticed that you received the June issue in early June, rather than late July!

We published the *Pharmacy Law Book* on behalf of the Board of Pharmacy; not only was this a service to our members, it also resulted in \$10,000 in additional revenue for the Association.

We set up a for-profit subsidiary, Mid-Atlantic DUR, which has been successful in acquiring contracts to perform retrospective DUR.

We supported the students both professionally and financially.

We held a retreat to educate benefit administrators about the prescription benefit. This began an ongoing dialogue between pharmacists and the purchasers of the prescription benefit packages.

On top of all these accomplishments, there were several activities begun this year that were especially important to me as President and also as a member of this organization.

First, MPhA completed the development of pharmacy practice guidelines for Maryland pharmacists. This accomplishment was the result of a resolution passed by the 1991 House of Delegates. These guidelines also fit into the mission of this professional association: that is, to promote the highest standards of professional practice in Maryland. The practice guidelines are available to all pharmacists through the MPhA office and will be published in the September issue of *The Maryland Pharmacist*. Please review them, and compare your practice to them. Keep in mind, that this is a dynamic document, which will require regular assessment for revision.

Second, we formed a Task Force for Cognitive Services Reimbursement. Our goal is to demonstrate that patients are willing to pay for cognitive services, including in-depth medication regimen review, teaching blood glucose monitoring techniques, and more. We are testing a "Pharmaceutical Care Consultation Request for Physicians" in several pharmacies. The participating pharmacists will be detailing their services to physicians and charging patients for these services separately from the dispensing fee. Most importantly, they will document in writing what was done for the patient.

Our next step will be to bill insurance companies for these services, and to examine the effect of these services. If you are interested in participating, please contact the Association office.

Like many of you, I have grave concerns about the future of our profession. I don't have to review all the threats with you -- but it certainly is threatening, even frightening, to see pharmacy gross sales continue to increase as net profits decrease.

I question whether pharmacy can continue to survive as a profession with its primary task of dispensing. I believe that the future of pharmacy practice lies in our ability to be successful in seeking reimbursement for our services; services that are above and beyond dispensing. Can we be successful today? Yes, in isolated instances. I am an example of a practicing pharmacist essentially making a living out of "cognitive services." How can we operationalize the concept of pharmaceutical care? How can we prepare our profession for the future?

Certainly, on Wednesday, there will be some engaging discussion about the future of pharmacy education in Maryland. I can tell you that I have developed a chronic headache from the multiple hats I have had to fit on my head this past year: as a full-time faculty member at the School of Pharmacy; as an active member of this professional association; and as a pharmacy practitioner. As your President this past year, I have been reticent to ardently express my own views about the all Pharm.D. issue. This is a professional association of practitioners, and yes, I consider myself a practitioner. I ask myself the same questions you should be asking yourself about the degree issue? How will an entry level Pharm.D. degree affect the profession? the economy? the patient? Do practicing pharmacists today need a Pharm.D.? What happens to Maryland graduates in 10 years if we don't go all Pharm.D.? How will this change affect me?

I also ask myself -- why **not** the Pharm.D.? Obviously, I made the decision for myself to go to school an extra two years, at my expense, to obtain the Pharm.D. And, after I obtained the Pharm.D., I have continued to work in community pharmacy, both in traditional and non-traditional settings. But I made the decision to obtain a Pharm.D., and I support the entry-level Pharm.D. because I believe in academic and professional excellence. It is the School of Pharmacy's role to strive for academic excellence; it is our role to strive for professional

excellence. I believe the School of Pharmacy is committed to this role.

You can listen to trade organizations' opinions; but keep in mind that these are opinions of corporate vice-presidents, and may or may not reflect what is best for the profession.

What is a profession? Webster has three definitions: 1) a calling requiring specialized knowledge and often long and intensive academic preparation; 2) the whole body of persons engaged in a calling, and 3) the act of taking the vows of a religious community. For the sake of argument, let's ignore definition three. Yes, we have intensive academic education in today's B.S. program. But the program is bulging at the seams. For the sake of the profession, our students deserve a doctoral level education; they deserve academic excellence.

Will we continue with the status quo, or will we support a decision to move our profession into the next millennium? Each of us must decide, as a professional, the direction our profession will take.

Now, on to my last agenda item as President. In the fall, MPhA, along with other pharmacy organizations is planning a Pharmaceutical Care Consensus Conference. The purpose of this Conference is to describe the optimal model for pharmaceutical care in Maryland; to identify the aids in and barriers currently existing for achieving that model, and strategies towards overcoming those barriers, and capitalizing upon those aids. Regardless of what happens on Wednesday, we, as an association, must continue to move forward as a profession; hopefully this Consensus Conference can give us some direction.

There were some goals that we did not reach this past year. The Freedom of Choice/Consumer Access bill failed in the legislature this year. But that's okay I had to leave some goals for our next president, Nick Lykos, to accomplish.

I believe we have taken great strides forward this past year, thanks to you, the members. Let's continue the trend. ■

---

The preceding report was delivered to the First Business Session of the House of Delegates on Monday, June 15, 1992 at the 110th Annual Convention of the Maryland Pharmacists Association.

# Important figures in diabetes care



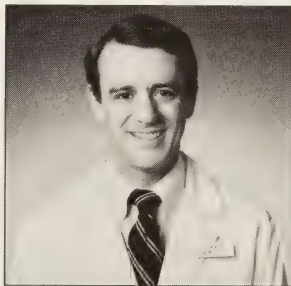
Diabetes is the **No. 7** cause  
of death in the US<sup>1</sup>

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Diabetes is the **No. 1** cause of new  
blindness in persons aged 20-74<sup>1</sup>

---



Pharmacists see patients with diabetes  
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These customers spend 3 to 8 times more  
annually in the pharmacy than persons  
without diabetes.<sup>2</sup>

---



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1. *Diabetes Surveillance, 1980-1987*. Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes*. Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

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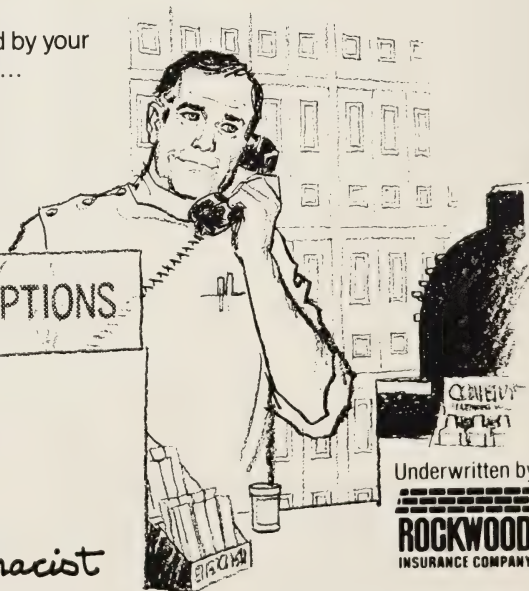
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# Executive Director's Report

David G. Miller, P.D.



Each year, it is my responsibility to report to the membership the actions taken by the MPhA Board of Trustees and the Association's standing, special and ad-hoc committees towards fulfillment of the policy and position statements adopted by the MPhA House of Delegates.

In 1991, 11 resolutions were adopted by the House of Delegates at its meeting on June 19 during the 109th Annual MPhA Convention. Each resolution is reproduced below, along with a brief overview of what was accomplished.

#### *1991 Resolution: Timely Notice*

The Maryland Pharmacists Association shall seek by regulation and legislation a requirement that all insurers, HMOs, third-party administrators, Medicaid and any other program that provides pharmaceutical benefits must notify that program's participating pharmacies of changes to the program's rules and requirements at least 30 business days in advance of the proposed change; and, that this legislation and regulation require that if the program fails to provide such notice, any claim submitted from the date of notice until 30 business days after the notice must be honored and paid in full under the program's guidelines in place before the date of notice.

The "timely notice" bill, House Bill 223, was introduced and passed in the 1992 legislature and was the only "anti" third-party legislation passed by any provider group. The bill takes effect July 1, 1992.

#### *1991 Resolution: Standards of Practice*

The Maryland Pharmacists Association shall define the standards of practice of pharmacy in the state of Maryland; and, that the Maryland Pharmacists Association work with the Maryland Society of Hospital Pharmacists and other pharmacy groups so that the standards of practice accurately reflect pharmacy's varied practice areas; and, that the Maryland Pharmacists Association make a standards of practice document available to every pharmacist in the state.

I am pleased to announce that, under the guidance of President Zuckerman and Chairman Bill Heller, the MPhA Principles and Guidelines for Pharmacy Practice were completed and approved by the MPhA Board of Trustees in May. This document, developed by a Committee comprised of representatives from MSHP, MACDS, and other groups, will appear in along with articles on patient counseling in the September 1992 issue of the *The Maryland Pharmacist*.

#### *1991 Resolution: Mandatory Patient Counseling*

Therefore, be it resolved that the Maryland Pharmacists Association oppose any regulatory or legislative activity that mandates patient counseling by pharmacists; and, Be it further resolved that the Maryland Pharmacists Association pursue the State's recognition of the standards of practice, developed by the Association, as sufficient to meet the requirements of the Federal Omnibus Budget Reconciliation Act (OBRA) of 1990.

After reviewing our draft standards of practice, the Maryland Medical Assistance Program believed it to be in their best interests to pursue legislation mandating patient counseling. Reluctantly, the MPhA supported their bill with our own amendments. One of these amendments was to require that the Department and the Board of Pharmacy must work with our organization in the drafting of any regulations that may arise from this new requirement. At that time, we will be using our principles and guidelines document.

#### *1991 Resolution: Commendations of Servicemen*

The Maryland Pharmacists Association honor and commend the pharmacists that served in the Persian Gulf in 1990 and 1991.

A request for names of service men and women who participated in the Persian Gulf Conflict appeared in the July/August 1991 issue of the MPhA monthly newsletter. Two names were obtained, Dr. William Grimm and Dr. Eric Baylus. Certificates of commendation, specially printed by MPhA, were sent to each of these Maryland pharmacists. In addition, MPhA participated with the APhA Foundation to obtain donations for a memorial plaque honoring members of the armed forces in the Korean, Vietnam, and Persian Gulf wars. So far, Maryland pharmacists have contributed more than \$450 to this effort.

*1991 Resolution: Smoke-free Pharmacies*

The Maryland Pharmacists Association strongly recommends and encourages all pharmacies be smoke-free and that implementation of this policy be accompanied with appropriate public education programs, including the conspicuous posting of signs.

To better educate pharmacists about this policy, and to encourage pharmacies to comply with this resolution, the January 1992 issue of *The Maryland Pharmacist* was dedicated to smoking. In addition to a tear-out poster asking patients not to smoke in the pharmacy, a guest commentary about smoking from Secretary of Health and Human Services Louis Sullivan highlighted several articles on smoking cessation products, techniques and services.

*1991 Resolution: Affiliation with ASCP*

The Maryland Pharmacists Association shall pursue "Affiliated Organization" status with the American Society of Consultant Pharmacists.

MPhA applied for affiliated organizational status with ASCP and was granted this status by that organization in October 1991.

*1991 Resolution: Preprinted Prescription Pads*

The Maryland Pharmacists Association shall seek legislation that would prohibit the use of prescription pads by prescribers that include either the advertising of a manufacturer of pharmaceuticals or the name of a drug product on the prescription pad or included within the packet of pads.

The MPhA Legislative Committee reviewed this resolution and, because of more pressing legislative priorities, recommended that legislation prohibiting such advertising be delayed until the 1993 or 1994 legislative session. The Committee will be gathering samples of advertising in prescription pads to support our legislation.

*1991 Resolution: Third Class of Drugs*

The Maryland Pharmacists Association shall seek legislation to mandate a phase-in "Sale by Pharmacy Only" period for all prescription legend medications which change to OTC status.

The Legislative Committee researched the third-class status of drugs by contacting the Maryland Poison Control Center, the Division of Drug Control and the Maryland

State Board of Pharmacy to inquire as to incidences of drug mis-adventures with over-the-counter products. No serious problems have occurred. Although no plans are to pass legislation have been formulated for the state, MPhA is working with APhA, NARD, NACDS and a coalition of health and consumer groups to pursue a third-class on a federal level.

*1991 Resolution: Expansion of Continuing Education Programs*

The number of live continuing education programs offered by the Maryland Pharmacists Association should be increased from two to six per year; and, that each program would be held in a different geographic area of the state and be non-repetitive; and, that the programs would be open to all pharmacists statewide and, whenever possible, be held jointly with local pharmacy associations; and, that at each program a segment would be included that informed all pharmacists in attendance the accomplishments of the Association and the goals towards which it is working.

In addition to the Annual Convention and the Mid-Year Meeting, MPhA sponsored a continuing education program in September 1991 for 154 pharmacists. In addition, the organization co-sponsored four other live programs with local pharmacy associations. At each of these meetings, MPhA promoted membership and its activities.

*1991 Resolution: CE Program Requirements*

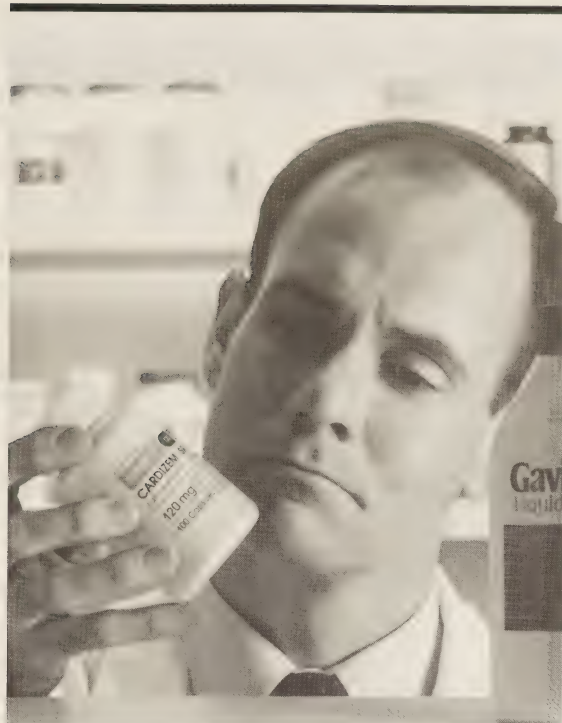
The Maryland Pharmacists Association by legislative action shall change the mandatory continuing education requirements to eliminate this exemption so that all pharmacists must earn continuing education credits immediately upon being licensed.

A request to make this change in §12-309 of the Maryland Pharmacy Act was sent to the Maryland State Board of Pharmacy in July of 1991. Because the continuing education legislation and regulations had only been in effect for a short time, and also because auditing of pharmacists' compliance with the law and regulations had just been implemented, the Board advised MPhA to wait to see if any other legislative changes would be necessary in this section. Once the Board has evaluated the continuing education legislation and regulations, MPhA will further pursue this policy.

*1991 Resolution: Calculators with the NABPLEX*

The Maryland Pharmacists Association request the Board of Pharmacy to propose this issue to NABP again; and, that since NABPLEX charges nearly \$250 to take the exam, that the NABP shall supply a simple calculator to be utilized by the examinees.

At MPhA's request, the Maryland State Board of Pharmacy introduced a resolution to allow calculators to be used by NABPLEX examinees. The resolution, considered at the National Association of Boards of Pharmacy's annual meeting, was defeated. ■



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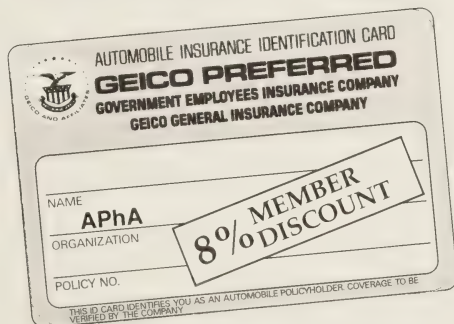
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# 1992 MPhA Resolutions

## Adopted at the 110th Annual MPhA Convention

### Resolution -- Mandatory AIDS Testing ..... Adopted, June 17, 1992

WHEREAS, the Maryland Pharmacists Association recognizes that AIDS is a deadly disease which health care workers, including pharmacists, are exposed to; and,

WHEREAS, any form of mandatory HIV testing would violate a pharmacist's right to choose whether or not to be tested; and,

WHEREAS, the vast majority of pharmacists do not have contact with blood or other body fluids during the care of their patients and therefore are considered to be in Category III under the Department of Labor Joint Advisory Notice HBV/HIV as published in the Federal Register.

THEREFORE, BE IT RESOLVED THAT, the Maryland Pharmacists Association opposes mandatory HIV testing of Category II and Category III pharmacists.

### Resolution -- All Pharm.D. Program ..... Adopted, June 17, 1992

WHEREAS, the University of Maryland School of Pharmacy is currently moving forward with plans to make the Pharm.D. degree the sole entry level degree offered; and,

WHEREAS, this move by the University of Maryland School of Pharmacy is based upon the anticipated educational needs of future pharmacists in providing quality pharmaceutical care and service to their patients,

THEREFORE, BE IT RESOLVED THAT, the Maryland Pharmacists Association reaffirms its position of support, as adopted in June 1990, for the establishment of the Pharm.D. degree as the sole entry level degree offered by the University of Maryland School of Pharmacy.

### Resolution -- External Pharm.D. Degree ..... Adopted, June 17, 1992

WHEREAS, current pharmacy practitioners are interested in pursuing a Pharm.D. degree,

THEREFORE, BE IT RESOLVED THAT, the Maryland Pharmacists Association supports a University of Maryland School of Pharmacy external Pharm.D. program for existing practitioners that gives significant credit for years of practice, that the program be based on continuing education credits earned and programs attended, that the program must be easily accessible to all pharmacists wanting to earn the degree, and that the cost of the program must be very reasonable.

### Resolution -- Out-of-State Licenses ..... Adopted as Amended, June 17, 1992

WHEREAS, the Virginia Board of Pharmacy requires that any pharmacy, including Maryland pharmacies, that deliver drugs to patients residing in Virginia be licensed with the Virginia Board of Pharmacy and pay annual fees as prescribed by law; and,

WHEREAS, the Delaware Board of Pharmacy requires that any pharmacy, including Maryland pharmacies, that deliver drugs to patients residing in Delaware be licensed with the Delaware Board of Pharmacy and pay annual fees as prescribed by law; and,

WHEREAS, the citizens of Maryland should also be afforded the protection against unregulated out-of-state pharmacies by requiring a copy of the most recent inspection by their State Board of Pharmacy be submitted with their annual licensing fee; and,

WHEREAS, the Maryland Board of Pharmacy will be in the very near future self-sustaining and will require fees to offset their expense;

THEREFORE, BE IT RESOLVED THAT, the Maryland Pharmacists Association recommend to the Maryland Board of Pharmacy to seek similar legislation as our sister states of Virginia and Delaware have enacted, and

—BE IT FURTHER RESOLVED THAT, the Maryland Pharmacists Association support the passage of such legislation. The Maryland Pharmacists Association seek legislation to require out-of-state pharmacies delivering prescription drugs to Maryland citizens within the state to obtain a pharmacy permit from the Maryland Board of Pharmacy and to adhere to the pharmacy laws and regulations of the State of Maryland.

**Resolution -- Resolutions Committee** ..... Tabled, June 17, 1992  
*WHEREAS*, the purpose of the MPhA House of Delegates is to establish policy and future direction for the Maryland Pharmacists Association in a democratic manner; and,

*WHEREAS*, the involvement of members in the policy making process is essential for maintaining the democratic process; and,

*WHEREAS*, the debate between opposing points of view are also integral to the democratic process;

*THEREFORE, BE IT RESOLVED THAT*, the House Resolutions Committee shall:

- 1) Review, discuss, and recommend a position to the House of Delegates for each resolution sent to the House Resolutions Committee by any active member.
- 2) The Committee may recommend one of the following positions for a resolution: adopt, defeat, refer to committee or table. The Committee may also request the withdrawal or redrafting of any motion. In the event that the member submitting the resolution declines to withdraw or edit the resolution, the Committee shall recommend a position on the resolution as presented.
- 3) The House Resolutions Committee is empowered to draft resolutions and recommend positions on those resolutions it creates. The House Resolutions Committee is also empowered to determine the order in which resolutions shall be presented to the House of Delegates after consultation with the Speaker of the House.

*BE IT FURTHER RESOLVED THAT*, this policy shall be incorporated into the next revision of the Maryland Pharmacists Association's bylaws.

**Resolution -- Delegates At Large** ..... Referred to Committee, June 17, 1992

*WHEREAS*, the purpose of the MPhA House of Delegates is to establish policy and future direction for the Maryland Pharmacists Association in a democratic manner; and,

*WHEREAS*, the involvement of members in the policy making process is essential for maintaining the democratic process; and,

*WHEREAS*, the current system by which the Speaker of the House of Delegates appoints twenty at-large delegates places undue burden on the Speaker and ultimately results in some members being unable to participate in the policy making process,

*THEREFORE, BE IT RESOLVED THAT*, the limit of twenty at-large delegates and their manner of appointment is hereby rescinded; and,

*BE IT FURTHER RESOLVED THAT*, any active member of the Maryland Pharmacists Association is entitled to serve as an at-large delegate, with full rights and privileges as a delegate as outlined in the MPhA Bylaws, provided that they register with the Secretary of the House of Delegates at least one (1) hour before any meeting or session of the House of Delegates; and,

*BE IT FURTHER RESOLVED THAT*, this policy shall be incorporated into the next revision of the Maryland Pharmacists Association's bylaws.

**Resolution - Recycling of Rx Containers** ..... Adopted as Amended, June 17, 1992

*WHEREAS*, recycling is becoming a required practice and is a sound ecological necessity; and,

*WHEREAS*, during the course of a regular work day, every pharmacist discards large amounts of plastic material; and,

*WHEREAS*, some recyclers require that the plastics being recycled be sorted by types of plastic;

*THEREFORE, BE IT RESOLVED*, that the Maryland Pharmacists Association should solicit a resolution by the national pharmacist and pharmaceutical manufacturing organizations that they phase in a uniform use of only one type of plastic for the bottling and packaging of procedures to facilitate recycling of pharmaceutical products's bottling and packaging because we care for our patients and we should also be able to show our care for our environment.

**Resolution -- Equal Access to Pharmacy Care** ..... Adopted, June 17, 1992

*WHEREAS*, there is a movement towards restricted networks which limit pharmacy participation; and,

*WHEREAS*, the driving force behind these limited networks is cost containment at the expense of quality of care; and,

*WHEREAS*, these limited networks are frequently inconvenient to the recipient and often interrupt longstanding professional relationships between members and these community pharmacists;

*THEREFORE, BE IT RESOLVED*, that MPhA supports the concept of equal access for pharmacy care and that the MPhA continues to support the passage of such legislation.

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## Professional Affairs Committee

William Heller, Chairman



### Committee Members

Calvin Alt, Jr.  
Robert Beardsley  
Alisa Billington  
Joe DeMino  
Donald Fedder  
Jerome Fine  
Kathleen Gauthier  
Simeon Georgiou  
Vince Ippolito  
Lisa Langer  
Gary Magnus  
Gail Rosen  
Gracemarie Smith  
Phillip Weiner

The Committee met at the Association Headquarters six times during the year to review comments received on drafts of various documents and to decide what to put into the succeeding draft.

The Committee commented extensively on draft regulations from the Board of Pharmacy concerning institutional pharmacy and long term care pharmacy practice.

Wrapping up the initiative of last year's chair, Ilene Zuckerman, the Committee concentrated its works on completing the review and compilation of what was initially called the "Pharmacy Practice Standards for Maryland." The creation of this document was the direct result of a policy established by the MPhA House of Delegates in 1991.

In addition to mail comments collected and committee meetings, a near-final draft was reviewed in a one and one-half hour long session at the Mid-Year House of Delegates Meeting. The finished document, retitled "Principles and Guidelines of Pharmacy Practice" was adopted by the Board of Trustees on May 14, 1992, and will be published in an upcoming issue of *The Maryland Pharmacist*.

The Preface to this document puts these principles and guidelines into perspective, as follows:

*These principles are not intended to codify the current practices of pharmacy, nor do they describe the best practices of pharmacy. Rather, they are intended to point to the better practices reasonably to be expected, considering the education of current pharmacists, the status of technology, and the willingness of the customer base to pay for it. The guidelines are intended to be useful suggestions in achieving the principles, but are not necessarily the only route to achievement. State and federal laws and regulations governing the control of drugs and devices and the practice of pharmacy form the base from which these principles and guidelines to the better practice of pharmacy ascend.*

The Principles and Practices is a living document, intended to be reviewed every year. The draft of a new section, entitled "Home Infusion" was provided during the year and will be processed next year. Other new areas targeted by the Committee's members included establishing and maintaining formularies, participation in drug utilization review, both prospective and retrospective, and issues related to continuing education.

The chairman of this committee, William Heller, was pleased to have had the excellent assistance of the staff throughout the year and the continued interest of last year's chairperson, President Ilene Zuckerman. ■

## Legislative Committee

*James Tristani, P.D., Chairman*



### **Committee Members**

Arnold Davidov  
Donald Fedder  
Murhl Flowers  
Robert Martin, Sr.  
Kim and Ray Palasik  
Susan Redmer  
Howard Schiff  
Ernest Testerman  
Ellen Yankellow

The committee was given the assignment of passing four pieces of legislation this past year, plus monitoring numerous other bills which impact our practice to various degrees. Our legislative goals were: patient counseling; require timely notice from third-party administrators, to increase penalties for forged prescriptions; and, equal access to HMO pharmacy networks.

**Patient Counseling - SB 151** This bill was actually a Health Department bill designed to bring the state into compliance with the OBRA act of 1990. The 1990 act requires patient counseling of medicaid patients under a set of guidelines set down by HICFA in order for the State of Maryland to continue to receive 60 million dollars in funding. Although most pharmacists feel that the federal agencies should not dictate how we practice professionally the committee was keenly aware this bill would pass. Through the efforts of our Director, Lobbyist Robin Shaivitz and the committee as whole amendment were proposed and adopted by the legislature to lessen the restrictive tone of the original bill. It is noteworthy note not one amendment by any other organization was accepted.

**Timely Notice - HB 223** This piece of legislation was sought to prevent all third party payers from continually changing plan rules and requirements with either little or no notice. Testimony presented by Director Miller showed documentation of third party payers implementing plan changes before notice was given to pharmacy providers. This documentation along with some lobbying of individual legislators was instrumental in obtaining 30 days notice before changes may be implemented.

**Forged Prescriptions/Penalties - HB 285** This bill was designed as a response to the Governor's Drug Commission which recommended triplicate prescriptions as a method to combat the serious prescription drug abuse problem. Before supporting the implementation of such a plan the MPhA voted to ask the legislature to increase penalties from a misdemeanor to a felony. The legislation supported by pharmacy and law enforcement agencies throughout the state had no opposition from any source during legislative hearings.

It passed the Senate by a 34-8 vote. However, the House Judiciary Committee composed mainly of lawyers decided that the problem was not serious enough to warrant the increase expense to the State to prosecute and house these offenders.

**Equal Access - SB 230/HB 334** This bill called for HMO's to open their networks to any pharmacy requesting the existing contract in effect at that time. It was the number one priority of the director, our lobbyist and members of the Legislative Committee. The bill was opposed by virtually the entire health maintenance field and other insurers.

The legislation was considered first by the Senate and by an extensive lobbying effort, directed by David Miller and Robin Shaivitz, numerous community pharmacists exerted pressure on their legislators. This resulted in Senate passage of the bill.

The House fight for passage of the bill again revolved around the House Environmental Matters Committee Chairman Ron Guns', of Cecil County, steadfast opposition to this bill. His opposition is based on the belief that a legislative precedent would be set that would allow other health care providers to seek the same legislative relief.

Again, after an intensive legislative lobbying effort by many pharmacists, particularly Ernest Testerman of Cecil County and Arnold Davidov and Ellen Yankellow of Baltimore who made numerous trips to Annapolis to directly lobby chairman Guns' committee, enough votes were believed to be secured for committee passage.

Due to a series of unanticipated events, such as intervention by the Speaker of the House and others, this bill was defeated by one vote. The manner in which this piece of legislation was defeated has led to complete revue of the entire legislative lobbying process by our organization and changes will be made.

#### Other Legislation of Note

In addition to these four main goals, MPhA also monitored several bills of importance to pharmacists. These included:

SB 655 - This bill allowed the Board of Pharmacy have fiscal independence from the state budget. This prevents the state from using pharmacy fees as revenue enhancer (tax) and allows the Board monies for increase in staff needed to serve the states pharmacists.

SB 355 - The Maryland Chamber of Commerce was responsible for legislation being introduced that would in essence make workman compensation prescription a third party. This bill was so poorly conceived and unworkable that pharmacists would not take the chance of filling this type of prescription. This bill was defeated. It is noteworthy that the Chamber of Commerce continues to introduce pharmacy legislation without input from pharmacists. I would urge any members to voice their concern to an appropriate source.

A complete listing of the bills monitored by MPhA appears in the June issue of *The Maryland Pharmacist*.

This legislative session was very difficult one. The legislators were pre-occupied with the States financial woes and redistricting and were not in a very receptive

mood. Our organization continues to excel in the passage of legislation of a professional nature. Economic matters are a different story. We continue to struggle upstream against organizations that are better funded than ours. The loss of the Equal Access Bill is a prime example of our being out muscled. It must be decided whether or not we are to become major players on economic legislation by committing the money and people resources needed to achieve our goals.

The coming year will see our return to the legislature for Equal Access, the banning of prescription samples, pharmacy only sales of prescription medication changing to OTC status, and mandated compensation for cognitive services. With the proper economic and people resources, these benefits to our practice may be achieved.

I would like to thank all the members of our organization who contributed to our successes this past year and I hope to work with them again. ■

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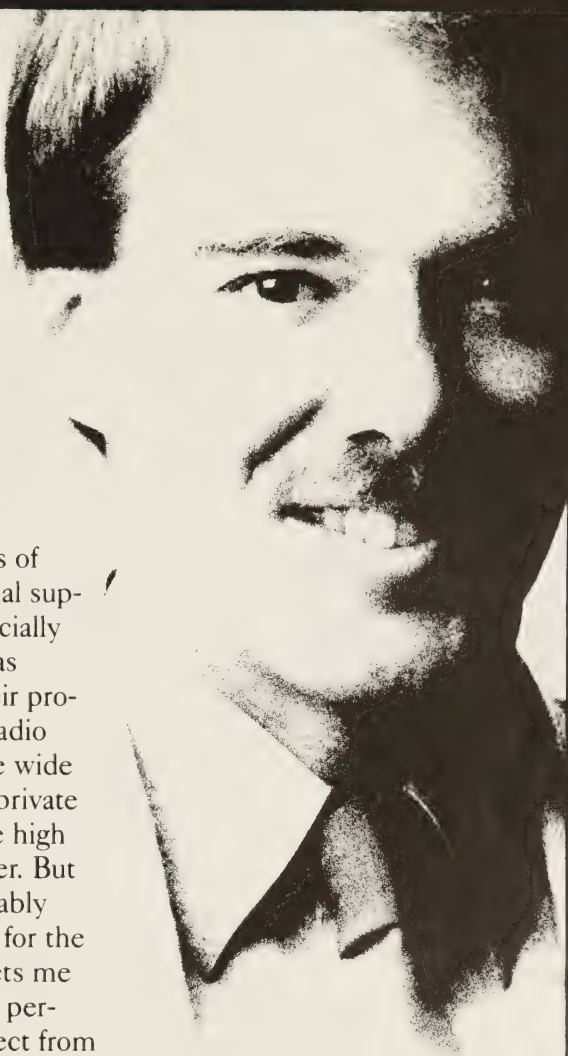
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## Third Party Committee

*Phillip Marsiglia, Chairman*



### ***Committee Members***

Harvey Goldberg  
Leonard Goldberg  
Robert Kabik  
Charles Muendlein  
Avi Pelta  
James Terborg  
Huseyin Tunc  
Gary Wirth

Because of the dynamic nature of the third party arena, 1992 has been a busy year. The committee has met three times as a full committee and more frequently in sub-groups with Medicaid, Blue Cross and the Legislative Committee.

One sub-group was the Blue Cross - MPhA Advisory Committee. This committee was reestablished last year after several years of inactivity. Unfortunately, only one meeting was held this year before Blue Cross decided to dissolve the committee. Considering the extensive list of unresolved issues with Blue Cross, it was most disheartening to close such a potentially valuable line of communication.

The Medical Assistance - Pharmacy Liaison Committee, also a sub-group of the Third Party Committee, met on a monthly basis with administrators from the Maryland Medicaid program. Because of the current financial crisis in the State, much of the discussion related to cost containment fostered with the Department, pharmacy was spared any significant program cuts and was actually granted a 25 cent fee increase. Other areas of discussion with Medicaid concerned changes to the Pharmacy Assistance Program formulary, adoption of new rules for the dispensing of H2 antagonists and a mass adjustment for incorrectly paid IDC prescriptions. Currently we are working with the Department on the development of an on-line adjudication and concurrent DUR review system. If implementation goes as planned for January 1993, Maryland will become the first Medicaid program with an on-line capability.

In other areas, the committee is working with our legal counsel to investigate if the Insurance Commissioner is enforcing laws as they relate to the establishment of unequal playing fields regarding Rx co-pays and dispensing limitations. Counsel is also investigating if the Commissioner has the authority to regulate the charging of processing fees by third party processors.

Finally, this committee has consulted with the Legislative Committee concerning MPhA sponsored legislation which relates to third party issues particularly Consumer Access/Freedom of Choice and timely notice. ■

## Member Services Committee

*Howard Schiff and Ellen Yankellow, Co-Chairs*



### **Committee Members**

Elwin Alpern  
Lynette Bradley  
Diane McNally  
Melvin Rubin  
Howard Schiff  
Tony Tommasello  
Rene Williamson  
Beverly Yachmetz

Under the guidance of President Zuckerman, a number of smaller MPhA committees were joined together under one new committee -- the Member Services Committee. This new organization enabled us to form sub-committees as needed and to tap into the additional members serving to accomplish several important tasks.

This year, the Member Services Committee set membership promotion as its highest priority. After conducting four focus groups around the state with both member and non-member pharmacists, the Committee planned five different member promotional campaigns. These included: 1) a discounted first-time membership to any hospital pharmacist who belonged to the Maryland Society of Hospital Pharmacists but not MPhA; 2) a mailing to all non-resident Maryland licensees; 3) a special promotion to all UMAB School of Pharmacy faculty with a dollar-for-dollar match by the School; 4) two membership telethons; and 5) a discounted membership to any non-member who attends an MPhA sponsored continuing education program.

The membership telethons, strongly supported by the volunteer efforts of pharmacy students, Board of Trustee members, and committee members, were held in January and May of 1992. The January telethon reached out to all 1991 members who had not renewed their membership in MPhA for 1992. This telethon resulted in a decline in our membership attrition rate for 1992 of more than 62%! Our second telethon was the direct result of one of our focus group recommendations -- reaching out to chain pharmacists. Volunteers called more than 75 chain pharmacies throughout Maryland. That telethon resulted in a commitment from 58 pharmacists to join MPhA. The Member Services Committee plans to repeat this successful promotion again soon.

In addition to these innovative promotions, the Member Services Committee is also planning an elaborate membership promotion to all Maryland pharmacists this month. It will offer a 1/2 year discount in dues -- an idea that has worked very well in the past.

The Member Services Committee is pleased to report that MPhA's membership has increased by 11.2% in the past year. We believe that this increase is the direct result of the strong volunteer commitment by the members of the Committee, the support of the MPhA Board of Trustees and staff, and the many members in the organization who are promoting the Association.

One another major accomplishment of the Member Services Committee this year was the establishment of the Pharmacists Rehabilitation Committee (PRC) as a separate entity. With the cooperation of the School of Pharmacy and MSHP, the PRC now has a structure identical to the Maryland Continuing Education Coordinating Council with MPhA, MSHP and the School acting in an advisory and fund-raising capacity. We believe that this new structure will enable the PRC to better manage the confidential nature of its work.

As previously stated, the Member Services Committee formed several sub-committees to carry out specific tasks. Their reports appear below for your review.

### **Publications Sub-Committee**

The major focus of the Publications Committee over the past year was to create a schedule of journals which are centered around specific topics. In addition, the plan included continuation of the standard journals such as the third-party issue, legislative wrap-up issue and the convention issue. The journal focus topics were selected by the previous publications committee. This year the committee was an ad hoc type committee to explore the new design and to draw on the expertise of the individuals as well as special interests in particular topics.

The format changes are hoped to increase advertising revenues by targeting specific vendors. In addition, the new format is hoped to increase reader interest by presenting a variety of articles with a central theme.

### **Continuing Education Sub-Committee**

Continuing education seminars sponsored by MPhA were held in September 1991, February 1992 and at the annual convention in June.

The fall seminar, "Advances in Cardiovascular Medicine," sponsored by Knoll, was held on September 22, 1991 at the BWI Sheraton International Hotel. 120 pharmacists attended and each received 5 C.E. credits.

The Mid-Year Meeting at the Loews Annapolis Hotel on February 9, 1992 was a complete success. 250 pharmacists attended from all areas of the state. 5.5 C.E. credits were offered for the complete program. The morning featured the seminar "New Drugs of 1991" presented by Dr. Daniel Hussar from the Philadelphia College of Pharmacy. Afternoon events included the seminar "Overcoming Cultural Barriers in Communication," presented by Dr. Rose "Cookie" Cogan. The crowd went crackers over Cookie.

Continuing education to be presented at the Sheraton Hotel convention in Ocean City range in topics from patient counseling to anxiety disorders. In all, 12 C.E. credits will be offered.

The members of the C.E. committee consists of Howard Schiff, Arnold Davidov, Mel Rubin and Beverly Yachmetz. Schiff, Davidov and Rubin also serve as the MPhA representatives for C.E.C.C.

Efforts are underway to increase the number of live programs offered by the MPhA.

### **Meetings and Trips Sub-Committee**

Our 1991 Convention at the Sheraton in Ocean City was extremely well attended. Our registration receipts were \$20,074.00 with additional corporate support of \$11,261.06. Our Trade Exposition receipts were \$17,350.00. Our net revenue for the 109th Annual Convention was \$15,190.30.

The 1992 Mid-Year Meeting was held on February 9, 1992 at the Loews Annapolis Hotel. The more than 250 pharmacists in attendance, along with strong financial support, pushed our net revenues to their highest ever for an MPhA Mid-Year Meeting -- \$5,512.06!

This year's MPhA sponsored trip was a six island cruise of the Caribbean aboard the "Monarch of the Seas." Seventy-six people took advantage of the discount cruise rates negotiated by MPhA and Towson Travel. Revenues from the cruise was \$4,069.00. Next year's trip/cruise is planned for January 1993. We are planning to visit Aruba.

### **Scholarships/Awards**

Selected by the Past Presidents' Council, as set forth in the 1991 MPhA Bylaws Revision, were the awards and scholarships offered by MPhA. This year, voluntary contributions from members to the Scholarship Fund came to \$3,315. The Scholarship Fund now stands at \$17,619.52.

Three PEP Scholarships of \$300 each were given this year. The purpose of these scholarships is to aid financially needed pharmacy students during their PEP rotations when they are unable to obtain other income. More than 32 students applied and the selection was very difficult. The 1992 scholarships were given to: Catherine Campbell, Deonna Austin, and Sandy Antezana.

The Harry D. Kaufman Award for service to the pharmacy and/or community by a pharmacy student was awarded to Lynette Bradley.

The Bowl of Hygeia Award, given for outstanding service to the community by a pharmacist, was awarded to Robert Martin, Sr.

Ralph Quarles was selected to receive the Seidman Distinguished Achievement Award, given for exemplary service to pharmacy over a career.

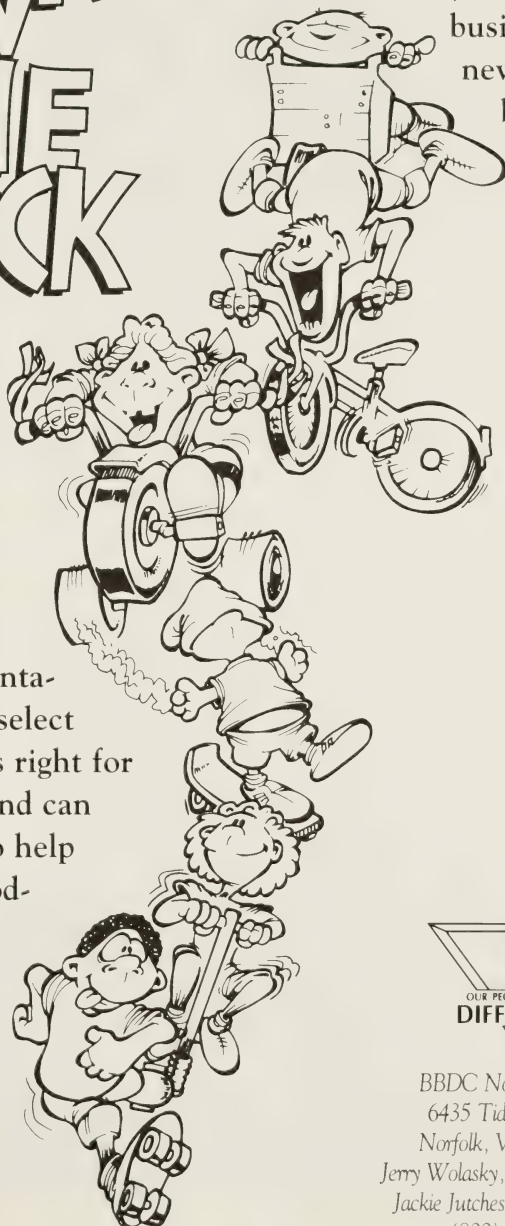
The Marion Merrell Dow Distinguished Young Pharmacists Award was given to Kathleen Gauthier.

Betty Alpern, president of MPhA's Spouses Auxiliary for the past several years, was selected as the 1992-1993 Honorary President. ■

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# Continuing Education

This continuing education series is provided to MPhA members as a source of continuing education credit. The Maryland Pharmacists Association is approved by the Maryland Board of Pharmacy as a provider of continuing pharmacists' education in this state. To earn 1.0 contact hours of credit (0.1 CEU) toward relicensure, refer to the instructions and quiz on page 30.

## Correspondence Course

### Update on Sunscreens: Part II

by J. Richard Wuest, R.Ph.,  
Pharm.D.  
Professor of Clinical Pharmacy  
University of Cincinnati  
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.  
Professor of Pharmacology  
and Toxicology  
Ohio Northern University  
Ada, Ohio

#### Goals

The goals of this lesson are to:

1. discuss the therapeutic properties of sunscreen product ingredients, and list factors that affect their usefulness; and
2. report contemporary information relevant to OTC sunscreen products.

#### Objectives

At the conclusion of this lesson,

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successful participants should be able to:

1. exhibit an understanding of terms relevant to OTC sunscreen products and their ingredients;
2. choose an appropriate sunscreen when a specific request is made;
3. choose from a list, information that best describes pharmacologic and toxicologic properties of sunscreen product ingredients; and
4. select appropriate information to counsel patients on concerning the correct use of sunscreens.

This lesson is the second part of a two-part series on sunscreens. Part I discussed ultraviolet light and the photodermatologic damage it causes to human skin. It defined the characteristics of specific wavelengths of ultraviolet radiation, and presented a summary of physiological effects to be expected following exposure to each of them. It also differentiated sunblocks from sunscreens, and explained the

meaning of sun protection factor (SPF) and phototoxic protection factor (PPF) values.

#### Sunscreens — A Review

Not all that glitters is gold! There is strong indication that even brief exposures to the sun can harm skin of some persons. And even though a brief exposure may not cause an acute burn or injury, the skin never forgets an injury! The greatest danger is that the chronic effects of overexposure are cumulative and persist for life. Indeed, there are over 40 identified pathologies that are known to be caused by exposure to solar radiation.

Of special importance is the recent finding that ultraviolet A (UVA) radiation is more damaging than previously believed, and has greater potential than UVB rays to cause serious health hazards. The current popularity of tanning salons has increased the potential for skin damage. Tanning lamps emit primarily UVA radiation. Each day more than one million Americans visit one of the more than 20,000 tanning salons in the U.S. Reasons for emphasis on protecting the skin against UVA rays are summarized in Table 1.

#### Substantivity

The ability of a sunscreen to bind with the stratum corneum and resist removal by sweating, exercising or

Table 1

#### Reasons for Protecting the Skin Against UVA Radiation

- UV intensity varies with the latitude, season, and time of day, but UVA varies less than UVB.
- The percentage of UVA in solar radiation is greatest in the early morning and afternoon.
- At midday, 10 to 20 times more UVA than UVB reaches the earth's surface.
- UVA augments the carcinogenic effects of UVB.
- UVA causes histologic changes, including morphologic changes in Langerhans cells, and triggers release of inflammatory mediators.
- UVA stimulates photosensitivity reactions, and hastens the photoaging process.

swimming gives the product its substantivity value. Substantivity is a function of two variables: the sunscreen agent itself, and the vehicle. Products containing PABA or PABA esters are generally more substantive than those with other sunscreen agents.

FDA has established guidelines for substantivity. Claims that products are "water resistant" or "waterproof" mean that they will remain substantive to the skin and retain photoprotective efficacy for at least 40 minutes for the former, and at least 80 minutes for the latter, with moderate activity in water. The claim "resists removal by perspiration" is appropriate for both water resistant and waterproof sunscreens.

The vehicle used for a sunscreen product is extremely important. It largely determines the extent of dermal penetration, degree of absorption by proteins of the stratum corneum, and extent of loss of sunscreen with perspiring and swimming. The vehicle also greatly determines consumer acceptance of the product.

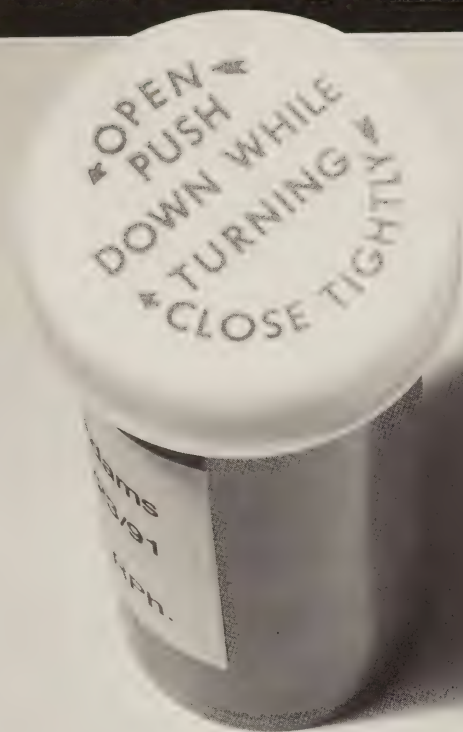
The ideal sunscreen should exhibit the following properties: (1) block most of the UVB and UVA radiation that reaches the skin; (2) prevent biochemical reactions that induce the sunburn reaction (i.e., block prostaglandin synthesis); (3) protect DNA of viable cells against changes that can lead to cytotoxicity; and (4) prevent photosensitivity reactions, photodermatoses, and photoaging, by filtering all UVA rays. There is a wide variety of photoprotection aids in the form of clear or milky lotions, gels, creams, or ointments to choose from (Table 2). By selecting a suitable sunscreen product, consumers can prevent many of the damaging effects caused by solar radiation.

**PABA and its Esters.** Sunscreen products that contain PABA esters have been the most widely used sunscreens in the U.S. A 5 percent solution of aminobenzoic acid (PABA) in 50 percent alcohol provides maximal sunscreen efficacy against all UVB radiation. However, it transmits most UVA rays. A major advantage is that PABA diffuses into the stratum corneum to bind with tissue protein in 30 minutes or less.

**Table 2**  
**Representative Sunblock and Sunscreen Products**

Product	SPF	Form	Ingredients
<b>Bain de Soleil</b>			
Body Silkening	25	Cream	Ethylhexyl p-methoxycinnamate Oxybenzone, Padimate O
Body Silkening Spray	20	Lotion	Same as above
Face Cream	25	Cream	Same as above
<b>Coppertone</b>			
Moisturizing Sunblock	25	Lotion	Ethylhexyl p-methoxycinnamate 2-ethylhexyl salicylate, Homosalate Oxybenzone
Moisturizing Sunblock	15	Lotion	Ethylhexyl p-methoxycinnamate Oxybenzone
Moisturizing Sunblock	8	Lotion	Same as above
Moisturizing Sunscreen	6	Lotion	Same as above
Moisturizing Suntan	4	Lotion	Same as above
Lite Tanning	4	Lotion	Ethylhexyl p-methoxycinnamate
Moisturizing Suntan	2	Oil	Homosalate
Lite Tanning	2	Oil	2-ethylhexyl salicylate
Dark Tanning Spray	2	Oil	Ethylhexyl p-methoxycinnamate
<b>Hawaiian Tropic</b>			
Baby Faces Sunblock	25	Lotion	2-ethylhexyl salicylate, Oxybenzone Octyl salicylate, Methyl anthranilate
15 Plus Sunblock	15	Lotion	2-ethylhexyl salicylate Oxybenzone, Methyl anthranilate
Sunscreen	10	Lotion	Padimate O, Oxybenzone
Protective Tanning	8	Lotion	Same as above
Dark Tanning with Sunscreen	4	Lotion	2-ethylhexyl salicylate, Methyl anthranilate
<b>Photoplex</b>			
Broad Spectrum Sunscreen	15	Lotion	Padimate O Butyl methoxydibenzoyl-methane
<b>Presun</b>			
39 Creamy	39	Cream	Padimate O, Oxybenzone
for Kids	29	Cream	Octocrylene, Oxybenzone, Octyl salicylate
29 Sensitive Skin Sunscreen	29	Cream	Same as above
23 Creamy	23	Cream	Padimate O, Oxybenzone, Octyl salicylate Octyl methoxycinnamate
23 for Kids	23	Cream	Same as above
15 Creamy	15	Cream	Padimate O, Oxybenzone
15 Sensitive Skin	15	Cream	Octocrylene, Oxybenzone, Octyl salicylate
8 Creamy	8	Cream	Padimate O, Oxybenzone
<b>Shade</b>			
Sunblock	45	Lotion	Ethylhexyl p-methoxycinnamate Octocrylene, Oxybenzone 2-Ethylhexyl salicylate
Sunblock	30	Lotion	Ethylhexyl p-methoxycinnamate 2-Ethylhexyl salicylate, Homosalate Oxybenzone
Sunblock	25	Gel	Same as above
Sunblock	15	Gel	Ethylhexyl p-methoxycinnamate Octyl salicylate, Oxybenzone
Sunblock	15	Lotion	Ethylhexyl p-methoxycinnamate Oxybenzone
<b>Sundown</b>			
Sunblock Ultra	30	Lotion	Octyl methoxycinnamate, Octyl salicylate Oxybenzone, Titanium dioxide
Sunblock Ultra	25	Lotion	Same as above
Sunblock Ultra	24	Cream	Padimate O, Oxybenzone
Sunblock Ultra	20	Lotion	Octyl methoxycinnamate, Octyl salicylate Oxybenzone, Titanium dioxide
Sunblock Ultra	15	Cream	Same as above
Sunblock Ultra	15	Lotion	Padimate O, Oxybenzone Octyl methoxycinnamate
Maximal	8	Lotion	Padimate O, Oxybenzone
Extra	6	Lotion	Same as above
Moderate	4	Lotion	Same as above

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The discovery of PABA esters was a significant advancement in modern sunscreen development. They can be incorporated into a wide array of product formulations. PABA esters are more acceptable than alcohol-based products because they are less irritating, more substantive, and more cosmetically elegant. Thus, consumers are more likely to comply with instructions.

**Benzophenones.** Benzophenones in common use include oxybenzone and dioxybenzone. These absorb light over a wide ultraviolet range. But the benzophenones are poorly substantive and require frequent reapplication.

**Cinnamates.** The effectiveness of cinnamate-containing products depends mainly on the activity of the vehicle to bind with the skin. Cinnamates do not bind with the skin and, therefore, have poor substantivity.

**Salicylate Derivatives.** Homosalate, ethylhexyl salicylate, and other salicylate derivatives have about one-third the absorbance of PABA. Consequently, they must be used in high concentration, and are usually used in combination with other sunscreen agents. They do not bind to the skin, nor are they easily removed by sweating or swimming.

**Dibenzoylmethane Derivatives.** These comprise the newest group of marketed sunscreens. Dibenzoylmethane derivatives block radiation throughout the entire UVA waveband. Therefore, they are sometimes referred to as full-spectrum sunscreen agents. Recent marketing of butyl methoxydibenzoylmethane (Parsol 1789) in combination with padimate O (Photoplex) provides, for the first time, a full-spectrum sunscreen product effective in blocking solar energy throughout most of the UVB and the UVA range. Photoplex, therefore, provides greater protection against UVA radiation than other sunscreens previously available. This is especially important in the 360 to 400 nm range where much of the sun's damage is concentrated. Other commercially available absorbent sunscreens did not provide that protection. Clinical trials have demonstrated significantly greater sunscreen protection with Photoplex than with padimate O alone, butyl methoxydibenzoylmethane alone, or a combination of padimate O and other commonly used sunscreens.

## Sunscreen Product Popularity

Many consumers use sunscreen products sporadically. Moreover, a vast number apparently do not understand fundamental points about them.

To illustrate, it has been documented that nearly two-thirds of consumers use a sunscreen *sometimes* during prolonged periods of sun exposure. But only one of seven *always* uses a sunscreen product when exposed to the sun. Only one of seventy-two persons surveyed could specify the SPF value of the sunscreen product they used. And among products cited, some were actually emollients, rather than true sunscreens. A reason given by 20 percent of respondents who seldom, or never, used a sunscreen was their desire to acquire a tan. Only 9 percent said they rarely spend time in the sun.

## Adverse Effects of Sunscreens

For the most part, sunscreen products are safe and seldom cause adverse reactions. Complications include erythema (redness), stinging and burning. Strangely, benzophenones and PABA derivatives are occasionally implicated in causing or aggravating photosensitivity reactions. Persons who are allergic to "caine"-type local anesthetics, thiazides, and sulfonamides, may experience cross reaction with PABA esters. Padimate O is considered to be the least involved of the PABA esters in initiating contact or cross sensitivity reactions.

Highly viscous products and those containing cinnamates and benzophenones are occasionally reported to aggravate acne.

Allergic contact dermatitis can also occur with fragrances and preservatives in OTC sunscreens. Vehicles such as triethanolamine stearate, or ingredients such as lanolin, almond oil, cocoa butter and antioxidants can also be sensitizing. Persons with a chronic photodermatosis condition (see Part I of this series) or past history of a topical eczema are most susceptible.

PABA may stain some clothing, especially white cotton, yellow to dark brown after exposure. PABA esters reportedly do not stain fabrics.

## Advising Consumers on the Proper Use of Sunscreens

Nearly everyone who spends a lot of time in the sun is a candidate for sunscreen protection. There is strong reason to believe that many, if not most, consumers do not understand how to correctly use sunscreen products, thus affording pharmacists a great opportunity to counsel them.

Sunscreen products must be applied 30 to 60 minutes prior to exposure, to achieve maximum effectiveness. This allows time for the product to penetrate the skin and maximize its substantivity. Reapplication after swimming, sweating or exercise will assure that the product will be effective for the length of time as calculated from its SPF value.

For the past several years, several manufacturers have been playing an "SPF numbers game" by marketing products with 20, 30, and even higher SPF values. Many authorities agree that sunscreen products claiming to have SPF values greater than 15 (Table 3) are unnecessary for most people). They may be suitable for individuals with Type I skin, or others who experience photosensitivity reactions following brief encounters with ultraviolet light. Persons requiring higher SPF value products should not indulge in sunbathing or outdoor activities where they are exposed to the sun. The high SPF-value products may give a false sense of security, since SPF-15 products already block more than 93 percent of UVB radiation. The SPF value identifies the degree of protection against UVB, *not* UVA rays.

Persons with known photosensitivity liability should take extra precaution to minimize problems during times of prolonged exposure to sunlight. It would be best to discontinue use of cosmetics and highly perfumed and fragranced soaps. They should avoid drugs and chemicals that are known photosensitizers. If they must use one of them they should be extremely careful and protect their skin against ultraviolet rays.

The quantity of sunscreen applied is extremely important. Directions for tests to determine SPF values require application of 2 mg/cm<sup>2</sup> of skin. Many people use an insufficient amount of product, resulting in less than expected protection. A sunscreen product's

**Table 3**  
**SPF Values and Skin Types**

Skin Color/ Complexion	Skin Type	Susceptibility to Sunburn and Suntan*	Recommended SPF to Avoid Sunburn
Very fair	I	Always burns easily; never tans	15 +
Fair	II	Always burns easily; tans minimally	15
Light	III	Burns moderately; tans eventually	10-15
Medium	IV	Burns minimally; always tans well	6-10
Dark	V	Rarely burns; tans readily	4-6
Black	VI	Never burns; becomes deeply pigmented	—

\*Based on 45 to 60 minutes exposure to midday summer sun without sunscreen protection or previous tan.

perceived ineffectiveness may, therefore, not be due to product failure, *per se*, as much as to improper application.

The following patient information will help pharmacists answer many of the most often asked questions about tanning and sunscreens.

1) Apply sunscreens liberally and evenly over all areas of the skin that will be exposed to sunlight. Begin 30 to 60 minutes before exposure. Allow it to dry before applying cosmetics or clothing. Reapply the sunscreen every 20 to 30 minutes or more often if swimming or perspiring heavily.

2) The SPF number does not specifically relate to the number of minutes or hours of exposure to the sun. It signifies a multiplication factor for the time an individual can stay in the sun, and it is different for every person. For example, an individual who would normally get a sunburn after 15 minutes in the sun could remain in the sun 4 times longer (1 hour) using an SPF 4 sunscreen product. With an SPF 8 product, the person can stay in the sun 8 times longer without experiencing a burn.

3) Sunscreen products claiming SPF values greater than 15 may offer little extra value over SPF-15 products. A pharmacist can discuss with you why this is so.

4) Reapplication of a sunscreen product does not protect skin beyond the daily time limit of the product as calculated from the SPF value. However, it does help prevent further burning.

5) Use a sunscreen product even on cloudy days. The sun's ultraviolet rays can still cause skin damage. Remember to use a sunscreen on all skin that will be exposed to the sun for even short periods if photosensitivity to drugs or chemicals is a problem.

6) Sunscreen products protect against burning. They do not promote tanning. Sunscreen users can tan without burning.

7) The difference between "water-proof" and "water-resistant" sunscreens is that water-resistant products must retain their efficacy for at least 40 minutes after submersion in water. Waterproof products must remain effective for 80 minutes after submersion in water.

8) A person who burns easily should minimize the time of exposure to sunlight during peak burning hours of 10 a.m. to 2 p.m. Reflective surfaces, especially concrete, sand, and water should be avoided.

9) If the skin seems to "burn" more easily than normal when exposed to sunlight, the cause may be due to a reaction to a drug, or some other chemical used on the body. If discomfort persists, a physician should be consulted for further advice.

10) The nose, helix (top) of the ears, lips, cheekbone area, scalp of persons with thinning hair, and shoulders are particularly sun-sensitive, and vulnerable to sunburn. Physical or chemical sunscreen products must be conscientiously reapplied often to these areas.

11) Itching, redness or a rash that develops while using a product are reasons to stop using it. A pharmacist or doctor can suggest an alternate product.

12) Since most individuals will experience nearly 70 percent of their total lifetime exposure to sunlight by 12 years of age, pre-adolescents should be protected from excessive exposure. Infants under 6 months of age should be kept out of direct sunlight. Sunscreens should always be used on children and adolescents while they are swimming or participating in other outdoor activities. It has been variously reported that a severe childhood sunburn increases the risk of skin cancer, later in life, by 50 to 70 percent.

13) Do not use alcoholic solution products on children under 12 years of age. They cause stinging, burning, and irritation.

14) Some of the physical sunblock products are marketed in a rainbow of bold, dashing colors. These vividly-colored products offer no therapeutic advantage over non-colored products. However, they may encourage children and young adults to use the products more generously, and more often.

15) The type of clothing that best protects from sunburn is tightly woven, preferably colored, fabric.

16) Skin cancer is a significant problem in this country. There are over 600,000 new cases yearly, with approximately 7,000 deaths. Using a sunscreen product as directed can help reduce these figures.



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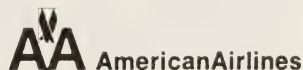
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# Continuing Education

## Continuing Education Quiz

## August 1992 -- Sunscreens Part II

Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by February 28, 1993. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

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Is this program used to meet your mandatory CE requirements?

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1. All of the following statements about substantivity are true except:
  - a. it refers to the ability of sunscreens to bind to the stratum corneum.
  - b. it allows for resistance to the removal of the sunscreen by sweating, exercise or swimming.
  - c. it is a function of the sunscreen agent, nor its vehicle.
  - d. it permits manufacturers to refer to their products as water resistant or waterproof.
2. Padimate O is a derivative of:
  - a. aminobenzoic acid
  - b. benzophenone
  - c. cinnamate
  - d. dibenzoylmethane
3. There is sufficient proof in the literature to warrant advising consumers to do all of the following when using a sunscreen except?
  - a. apply the product 30 to 60 minutes before sun exposure.
  - b. reapply it after swimming or sweating.
  - c. for type VI skin, use a product with an SPF value of 30 or higher.
  - d. if you have problems with skin allergy, the unscented and preservative-free products would be best for you.
4. A consumer requesting a sunscreen that does not contain padimate O, should be advised to select which of the following products.
  - a. Bain de Soleil
  - b. Photoplex
  - c. Presun Creamy
  - d. Shade Sunblock
5. Which of the following drugs or groups of drugs is least likely to cross-react with PAP esters?
  - a. aspirin
  - b. procaine
  - c. sulonamides
  - d. thiazides
6. Derivatives of which of the following provide the greatest substantivity?
  - a. aminobenzoic acid
  - b. benzophenone
  - c. cinnamate
  - d. dibenzoylmethane
7. Which of the following is true?
  - a. Sunscreen agents not only protect against burning, the also promote tanning.
  - b. The SPF number relates to a multiplication factor for the time individuals can be in the sun without burning and not the number of hours they can stay in the sun.
  - c. There is no need to use a sunscreen on cloudy days because clouds filter the UV light that is generated by the sun.
  - d. Reapplication of a sunscreen provides added protection beyond the daily time limit of the product's labeled SPF value.
8. People whose skin burns moderately and tans eventually have which kind of skin type?
  - a. Type I
  - b. Type III
  - c. Type V
  - d. Type VII

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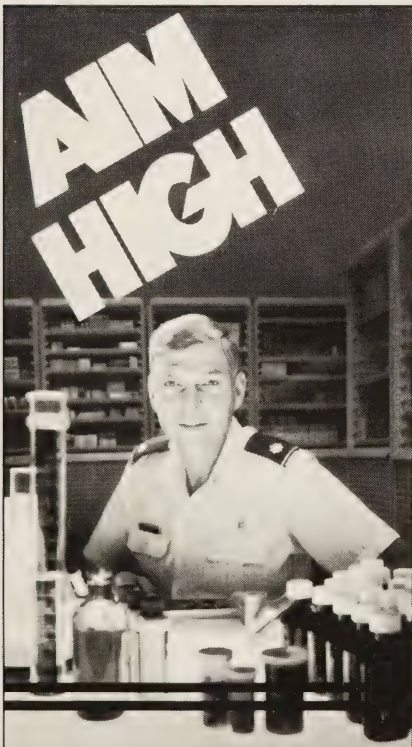
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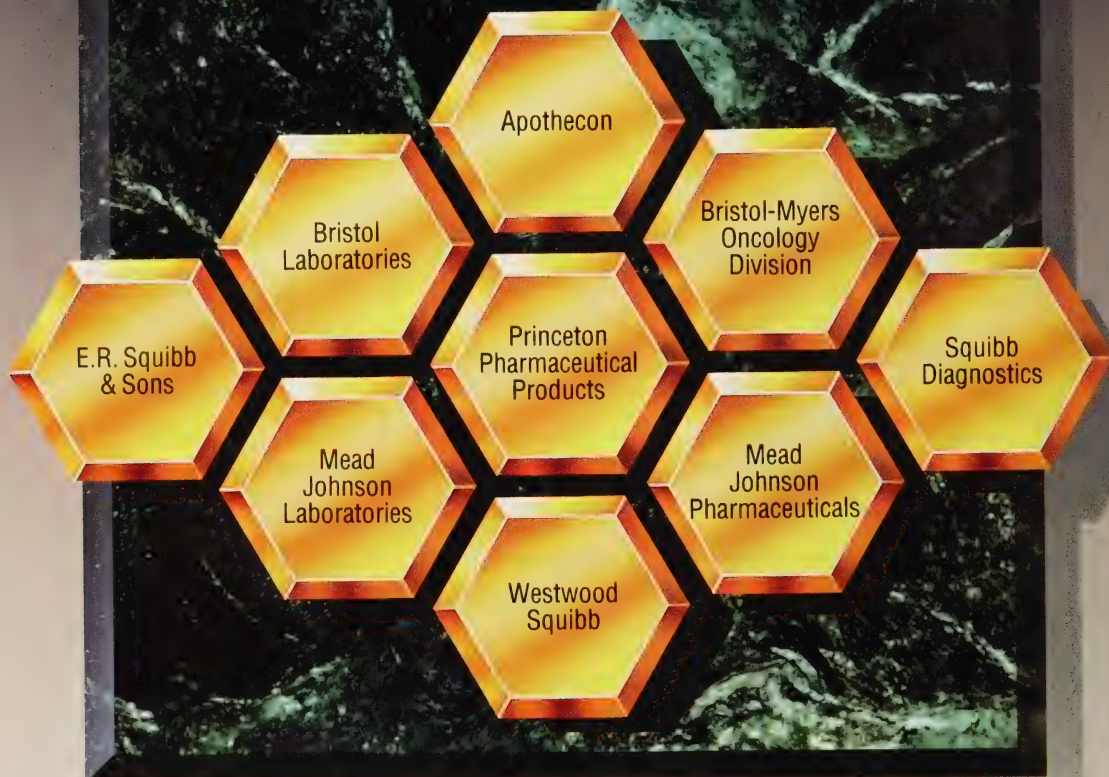
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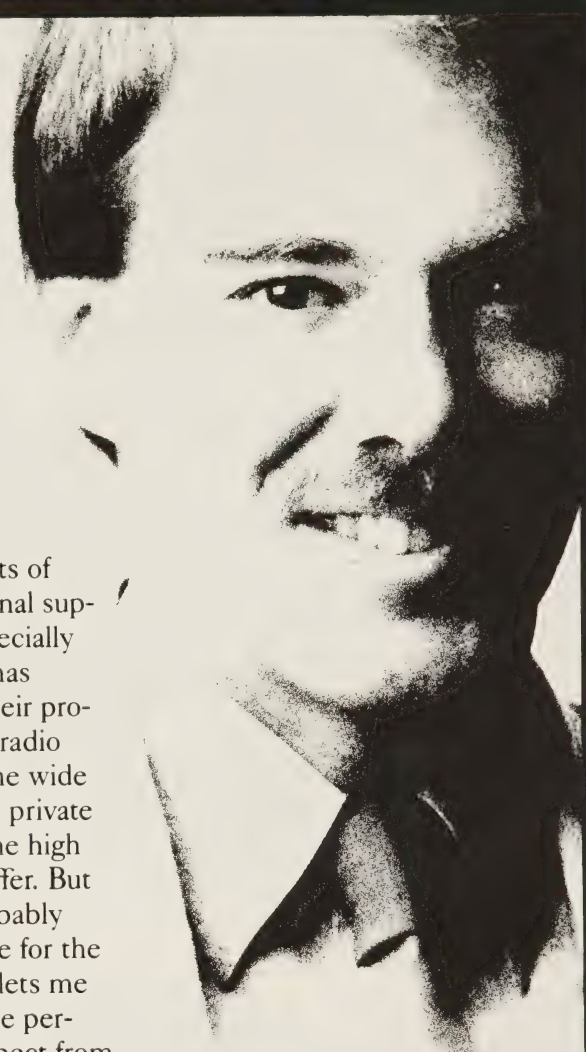
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VOL. 68

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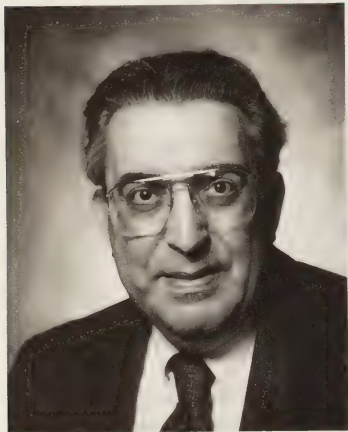
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Dorothy Levi, P.D.

Theodore S. Litwin, L.L.B.

## President's Commentary

Nicholas C. Lykos, P.D.



In May, Governor Shaefer signed into law Senate Bill 151 requiring pharmacists to offer, and provide when requested, patient counseling for all Medical Assistance recipients. This new law, the result of federal OBRA '90 legislation, will go into effect on October 1.

Like many of you, I ask myself "why?" Why should we as a profession accept legislation that tells us what we should be doing for our patients -- regardless of their class. How can we possibly provide these services? There isn't enough time, money, space, staff, etc..

Perhaps the answer to "why" lies in the past.

The methods for manufacturing and administration of pharmaceuticals changed dramatically from what was common in the late 1800's and early 1900's. The science of medicine was revolutionized with the development of penicillin and cortisone. Medication became more patient and dose oriented. And, slowly, pharmacy put aside the pill tile, the balance and finally the typewriter. The age of computers was upon us.

The advent of computers changed pharmacy forever. This new machine could spell very well, find data quickly and never ever forget anything. Other health professions, recognizing our ability to access information quickly, began to rely on pharmacists for assistance in prescribing and monitoring drug therapy.

The consumer movements of the 1970's instilled a new skepticism in Americans. Paternalistic health care professional's dictates were now open to scrutiny. And, as the cost of medications rose, patients began to ask strong questions of their pharmacists -- *What is the name of the medicine you are giving me? Why do I need it? Will it help me? When?*

And now, partly because it represents the largest payor of prescription drugs in the country and partly because it recognizes the importance of managing medications properly, Medicaid requires that the answers to these questions be given.

As we in Maryland begin to explore this new realm of pharmacy counseling, we have to answer the questions "How?"

Our immediate concern is that we are sufficiently educated to meet this new requirement. We expect our pharmacy schools to train all the new pharmacists. We look to various organizations and journals to educate the pharmacists who are now in practice. This assessment of ability extends into all pharmacy practice specialties. Hospital pharmacy directors are calling their staff together in workshops to understand what is expected of them and develop methodologies for implementing patient counseling services in their institutions. The community pharmacists are looking carefully at their own practice sites to see what environmental or procedural changes are necessary.

Communication and dialogue between pharmacist and patient must be natural and untroublesome. What are you doing to ensure that it is in *your* practice? ■

# Patient Counseling -- The Maryland Law

Reproduced below is the text of § 12-512, the new section of the *Maryland Pharmacy Act*, that now mandates certain patient counseling activities by pharmacists for Medical Assistance recipients. The law goes into effect on October 1, 1992.

## § 12-512. Mandatory Patient Counseling.

- (a) A pharmacist who provides prescription services to Medical Assistance recipients shall offer to discuss with each Medical Assistance recipient or caregiver who presents a prescription order for outpatient drugs any matter which, in the exercise of the pharmacist's professional judgement, the pharmacist deems significant, which may include the following:
  - (1) The name and description of the medication.
  - (2) The route, dosage form, dosage, route of administration, and duration of drug therapy;
  - (3) Special directions and precautions for preparation, administration, and use by the patient;
  - (4) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
  - (5) Techniques for self-monitoring drug therapy;
  - (6) Proper storage;
  - (7) Prescription refill information; and
  - (8) Action to be taken in the event of a missed dose.
- (b) The offer to discuss may be made in the manner determined by the professional judgement of the pharmacist, which shall include either:
  - (1) A face-to-face communication with the pharmacist; or
  - (2) At least 2 of the following:
    - (i) A sign posted so it can be seen by patients;
    - (ii) A notation affixed to or written on the bag in which the prescription is to be dispensed;
    - (iii) A notation contained on the prescription container; or
    - (iv) Communication by telephone.
- (c) Nothing in this section shall be construed as requiring a pharmacist to provide consultation if the Medical Assistance recipient or caregiver refuses the consultation.
- (d) A pharmacist must make a reasonable effort to obtain, record, and maintain, at the individual pharmacy, at least the following information regarding a medical assistance recipient:
  - (1) Name, address, telephone number, date of birth or age and gender;
  - (2) Individual history when significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and
  - (3) Pharmacist comments relevant to the individual's drug therapy which may be recorded either manually or electronically in the patient's profile.
- (e) This section shall apply only to Medical Assistance recipients presenting prescriptions for covered outpatient drugs.
- (f) The requirements of this section do not apply to refill prescriptions.
- (g) The Secretary, after consultation with the Maryland Pharmacists Association and the Maryland Association of Chain Drug Stores, shall adopt regulations in accordance with pharmacy practices in Maryland to implement the provisions of this section.

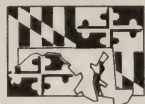
If any provision of this Act or the application thereof to any health care provider is deemed improper and would therefore cause the denial of any portion of the federal share of payment for Medical Assistance expenditures by the United States Department of Health and Human Services, then that provision shall be declared invalid, but such invalidity may not affect other provisions or any other application of this Act which can be given effect without the invalid provision or application, and for this purpose the provisions of this Act are declared severable.

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## The Art of Patient Counseling

*Thomas A Gossel, R.Ph., Ph.D., Professor, Ohio Northern University*  
*J. Richard Wuest, R.Ph., Pharm.D., Professor, University of Cincinnati*

One-half of all Americans take their medication incorrectly. They take it at the wrong time, in the wrong dosage, or take it concurrently with other drugs that interact.

Reports have demonstrated that patients expect personal attention and professional services from the pharmacist. Popular magazines and pharmaceutical association notices encourage the public to consult a pharmacist about their drug questions. Many physicians, and even the FDA, are advising Americans to establish a good rapport with a pharmacist.

This article examines pharmacist/patient communication. It illustrates the level of communication that currently exists, and offers suggestions for improvement.

### Pharmacists Talk to Their Patients

Pharmacists may have convinced themselves that they do communicate drug information to their patients. Most pharmacists talk to their patrons. They often begin an encounter with, "Hi, how are you?" or "May I help you?" Then, while completing the transaction they may inquire about the patient's family, or comment about the weather, sporting events or the world political turmoil. As they hand over the prescription, perhaps encased in a paper bag, they announce the price and indicate that "Your doctor says you should take one tablet stat, then three times a day. Call me if you have any questions about your script. And thank you for your business."

True indeed! The pharmacist talked to the patient and communicated his appreciation for shopping the pharmacy. But throughout the encounter, how much actual communicating of health-related information actually transpired? Did the patient truly understand what his medication was for? Did he understand what "stat" and "three times a day" meant? And what about OTC products or food or alcoholic beverage interactions? The patient may not think about these questions until he is ready to take his medication.

The 1975 Mills Commission Report indicated that pharmacists of the future will function as transmitters of information. The Commission reported that "...the greatest failing of pharmacy is its inadequacy as an information transmitting system." It urged pharmacists to

command principles of communication and use them because future pharmacists will dispense more information than medication. Unfortunately, studies have shown that as little as 5 to 6 percent of pharmacists' time is actually spent in consulting with patients.

Unconvinced that American consumers want more personal consultation and information? Then browse the shelves of any bookstore. Dozens of books have been written for the lay public that deal with various topics in health, including books that give specific information on prescription and OTC drug items. In fact, the Physician's Desk Reference (PDR) is one of the most popular books purchased by consumers and consulted in libraries across the country. It has appeared in the "Top 10" list of best sellers numerous times.

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***Pharmacists should try counseling a limited number of patients at first and then expand this schedule when they feel comfortable***

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The pharmacy literature stresses that good pharmacist/patient communication is paramount to professional practice today. Speakers at professional meetings also encourage good communication.

This information may be misleading to pharmacists who are interested in promoting communication. Communication specialists often assume that pharmacists can spend unlimited cash to hire others to perform many of the duties that will give them time to communicate, or to rearrange the pharmacy layout and purchase necessary furnishings. They also assume that pharmacists have time to attend college classes to learn basic communication skills, or, that they can start the first day to communicate effectively with all their patients. This article presumes none of these.

### Make the Commitment

Fast or Slow? There are two theories on how fast a communication program can be initiated. The first states that it is best to jump right in and counsel everyone. An advantage is that most mistakes will be made early on and pharmacists should benefit from extensive practice.

The other opinion stresses that pharmacists should begin slowly. Aristotle said "...you learn to play the flute by playing the flute!" In other words, pharmacists should try counseling a limited number of patients on the first day and maintain this schedule until they feel comfortable to expand. Or, they can concentrate at first on patients who receive certain types of medication, such as birth control regimens, antibiotics, or ingrown toenail remedies. Once mastered, the number of patients can be increased each day until all who need counseling receive it.

### Move Buffers and Barriers

Pharmacists' work areas have evolved around numerous barriers to good communication. Clerks represent one of the greatest barriers. A clerk assigned to the prescription receiving area may be the only person the patient encounters. The clerk meets and greets the patient, transmits the prescription to the pharmacist, then often returns the medication to the patient who then questions the clerk may respond and the pharmacist is never involved in the counseling process. Unfortunately, neither patient nor clerk knows what questions or information are pertinent. The pharmacist then is actually dispensing to the clerk.

The prescription countertop is another barrier. This is typically a 4 to 5 feet high, 2 to 3 feet deep structure that very effectively shields the pharmacist from his patients. It is frequently topped with promotional displays or lined along the rear with fast moving prescription items and a backlog of third-party record forms and remnants of yesterday's lunch. The poor patient just doesn't have a chance to communicate in this setting.

Then too, a raised platform behind this counter may elevate the pharmacist. Such elevations permit pharmacists to observe store activities and certainly raises them to positions of authority. But this subconsciously intimidates patients so they do not feel comfortable communicating on a one-to-one basis. So the setting for poor communication is further fostered.

Table 1 lists other barriers that interfere with open and effective communication. Many are obvious; others may not be. They should be identified and removed. Usually little or no expense is involved. Wholesaler merchandise can often be received in another section of the pharmacy

or kept out of sight until it can be put away. Seasonal display units that require floor space can be moved away from the pharmacy area. All other displays, signs, and objects that may distract a patient during communication should also be moved.

Merchandise and displays can be removed from the top of the prescription counter. And better yet, pharmacists can come out from behind the counter and stand at eye level with their patients to communicate with them.

Clerks can be instructed to receive and transmit a patient's prescriptions, but the medications should be dispensed directly by the pharmacist. This same clerk can

### *Common Barriers to Pharmacist-Patient Communication*

- High counters and pharmacy counter clerks
- Language barrier and ethnic differences
- PPIs, books, auxiliary labels and printed directions sheets
- Poor pharmacy layout; noisy or active waiting area
- Merchandise on floor or countertops that distract patients
- Other patients waiting who may overhear
- Age differences (i.e. young pharmacist in an older community)

engage in conversation with other patients who are waiting, to help temper their anxiety from having to wait for the pharmacist. More importantly, this makes the person with whom the pharmacist is currently serving feel more relaxed. High anxiety is correlated with low recall. Clerks should be instructed to answer all questions that do not relate to drugs or disease. The clerk's answer may be inadequate, incomplete, or even incorrect! Such questions should only be answered by the pharmacist.

### Make the Time

Moving barriers and clearing the aisles are easy. Finding the extra time to spend in counseling patients is

# Important figures in diabetes care



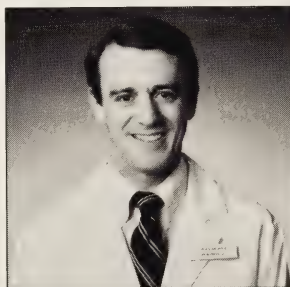
Diabetes is the **No. 7** cause  
of death in the US<sup>1</sup>

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Diabetes is the **No. 1** cause of new  
blindness in persons aged 20-74<sup>1</sup>

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Pharmacists see patients with diabetes  
**5** times more often than do physicians.  
These customers spend 3 to 8 times more  
annually in the pharmacy than persons  
without diabetes.<sup>2</sup>

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1. *Diabetes Surveillance, 1980-1987*. Atlanta, Ga: US Department of Health and Human Services, Division of Diabetes Translation; 1990: chap 3.
2. *Pharmaceutical Services for Patients With Diabetes*. Indianapolis, Ind: Eli Lilly & Company; 1987, 6-13.

another matter. An average patient counseling session should not require more than 1 to 2 minutes. But this time, multiplied by the number of patients needing it, adds up.

First, time is not found. It is made! Appoint another person to handle nonprofessional chores such as routine mail opening, stocking and dusting, checking in orders, building displays and answering the telephone. Even responsibilities such as completing third-party forms and price changing can be delegated to a trusted clerk. Professional journals and reading material can be taken home to study.

Ask a pharmacist colleague to spend a few hours observing you and recommend specific areas where a change in operation will produce significant time savings. Maybe you can return the favor to them or to another colleague.

Set definite goals for each day and prioritize them. List them on a 3x5 card, and keep it in view throughout the day, and proceed according to this schedule. Time efficiency experts claim that many minutes will be added to each working day by having activities planned in advance. These added minutes can then be devoted to patient counseling.

Many pharmacy journal advertisements and other printed pieces contain diagrams, figures and pictures that make excellent reference material for patient counseling use. Start a filing system for such information and keep it current. Use this to demonstrate specific points to a patient. A description of how gastric acid secretion is halted by an H2 blocker, for example, or how to correctly brush and floss the teeth will be more easily understood, and longer retained, when such illustrations are used.

The total time needed with each patient may be decreased by not having to verbalize some of the concepts. Only material that is easily understood and figures that are clear should be used. Extraneous words and artwork can distract the patient's attention, confuse him, and require the pharmacist to spend more time than necessary to explain what it all means.

Clear off the prescription counter work area. If there is not a separate office area or desk, set aside an unused portion of the prescription counter to serve this function. Separate it from the area devoted to prescription activities. Do not waste time repeatedly searching for

items that are usually covered beneath piles of papers, advertising copy, books, order forms and other collectibles. Items that aren't used each day should be moved elsewhere, out of the way. More precious minutes are thus gained.

Frequently dispensed medications should be brought closer to the work area. Log all movements into each bay or shelf area for a couple days. Decide which items need to be moved closer to the counter, then move them.

Schedule Patient Visits. Many days have periods that are busier than others. During these rushed times, counseling patients may be especially difficult. The following suggestion isn't appropriate for every patient, but it will work for some.

First, keep an accurate record of prescription filling activity during each 30 minute segment for the next 2 to 3 weeks. Record the number of prescriptions filled and indicate whether they are new or refills. A definite pattern of activity should emerge. Then, suggest to selected individuals who normally bring in refills during these busy periods that they may wish to come at another time. Or, ask them to call in their refill prescription number(s) in advance. When they do come in, you can spend more time discussing their health questions and drugs.

In one survey of pharmacy patients, 70 percent admitted that if the pharmacist looked extremely busy, they would not bother him with questions. And the majority indicated that unless more pressing circumstances prevailed, they would gladly come to the pharmacy when the pharmacist was not as busy.

### **Say it Correctly**

Health professionals communicate through a common language that is understood by other health practitioners. But it may mean little or nothing to a patient. Imagine a patient casually being told to take a "stat" dose of medication, or to take it "pc!" Pharmacists casually tell their patients the "The 'sig' on your script is..." and so on. Even medical terminology such as pediculosis, tinnitus, hyperkalemia or hypertension may confuse the patient.

But don't talk down to patients either. Use terms they can understand. Start by putting them at ease and tell them you are interested in making sure they fully

understand the directions.

Learn to communicate the ideas you want stressed and to elicit the specific information you need from a patient. To avoid misunderstanding and minimize incorrect or incomplete information being given, refer to the questioning techniques in Table 2.

### Label Instructions

Instructions on the label are also open for misinterpretation. Prescription labels that otherwise seem clear to both pharmacist and patient at the time of dispensing may be confusing at the time of administration. A study illustrated this point.

Outpatients in a clinic pharmacy were asked to interpret the labels on each of ten prescriptions. The labels contained commonly used phrases. For a prescription for propoxyphene HCl, for example, patients were instructed to "Take one capsule every four hours as needed for pain". They were encouraged to question the pharmacist to help clarify the directions. Questions relating to effectiveness, side effects, refills, drug interactions and other warnings and precautions were asked. But no one asked what "as needed" meant.

The patients were then asked to assume they took a capsule at 8 a.m. If pain were still present at 10 a.m., could another dose be taken? Approximately 20 percent responded affirmatively. In fact, when they were asked to state how many capsules could be taken each day, about half responded incorrectly with answers ranging from two to eight.

In another investigation, patients were asked to interpret the meaning of a label affixed to their antihypertensive medication which stated, "This prescription cannot be refilled." Seven percent believed it meant that the medication did not need to be taken any longer.

Similar confusion in label instructions still exists for some OTC products. For example, one young girl believed that the contraceptive jelly she purchased was to be spread on her breakfast toast. Months later when she learned otherwise, she also discovered why she had become a mother.

### Types of Questions

**OPEN ENDED:** Good way to open conversation. Example: "What other medication are you taking?" Questions cannot be answered yes or no.

**CLOSE ENDED:** Answered yes or no. Best to avoid since patient is forced into one of two answers.

**DIRECT:** Use when more specific information is needed. Example: "You mentioned that the directions were not clear. Which specific part is not clear?"

**SUGGESTIVE:** Questions suggest that something should or should not happen. Example: "This drug causes sedation. Did you feel tired?" Should be avoided unless they are the only means to get the patient started talking.

**REFLECTIVE:** Questions begin by commenting on the last few words of patient's statement. If patient remarks that "These tablets made me feel nauseous," then a reflective question could begin, "You feel nauseous...?" Question then would bring out more detailed information. People may feel positive about this type of questioning since it shows the pharmacist is really listening to them.

Table 2

Pharmacists should not assume that patients understand even the most simple terminology. In fact, the major reason people do not take their medication correctly is that they do not understand the directions. The pharmacist should explain the directions for prescription items and OTC medications, and use language that the patient understands. They should then ask that this information be repeated by the patient in his own words.

### Nonverbal Communication

The unspoken word is often more suggestive than the

spoken. People judge others by the visual impressions they leave. It was shown in one study that only 5 percent of an overall message is conveyed by the spoken word, 55 percent is transmitted by the tone and facial expressions, and 40 percent by body language.

Pharmacists who display a perpetually bewildered look, or always refer to a book or microfiche before answering a question, or constantly clear their throat before talking or keep their head bowed with eyes directed to the floor while talking, may give the impression that they do not know what they're doing. Even small gestures such as frowning the brow or scratching the head while studying the prescription may send negative vibrations to the patient.

#### Overview

Communication skills are developed through practice. Not all patients need counseling, but many do. Pharmacists can practice good communication on just a few patients at first and then expand.

Pharmacists should identify unnecessary barriers around the pharmacy and remove them. They should also initiate drug information rather than wait to be asked. Pharmacists can let consumers know that they are ready to serve them by displaying such notices throughout the pharmacy. By using their imagination to discover more ways to improve communication skills, everyone will benefit. ■

This article reprinted from the February 1989 *The Maryland Pharmacist*. Dr's. Gossell and Wuest's articles are sponsored through an educational program grant-in-aid from Searle.



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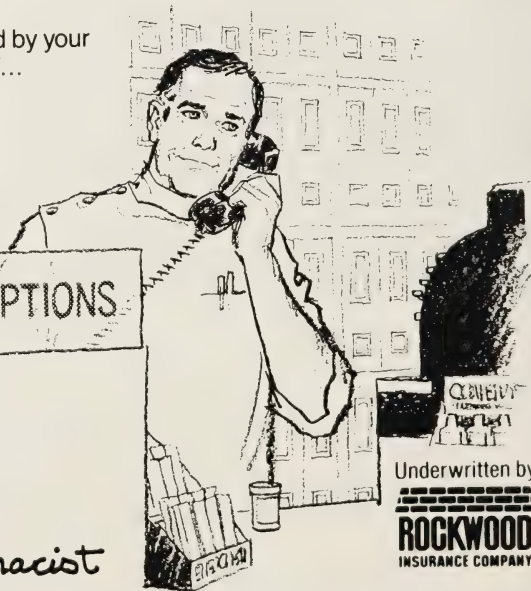
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**When and how do I take it?**

**How long should I take it?**

**Are there any side effects of this medicine I should be aware of?**

If you don't know the answers to these questions, ask to talk with the pharmacist!

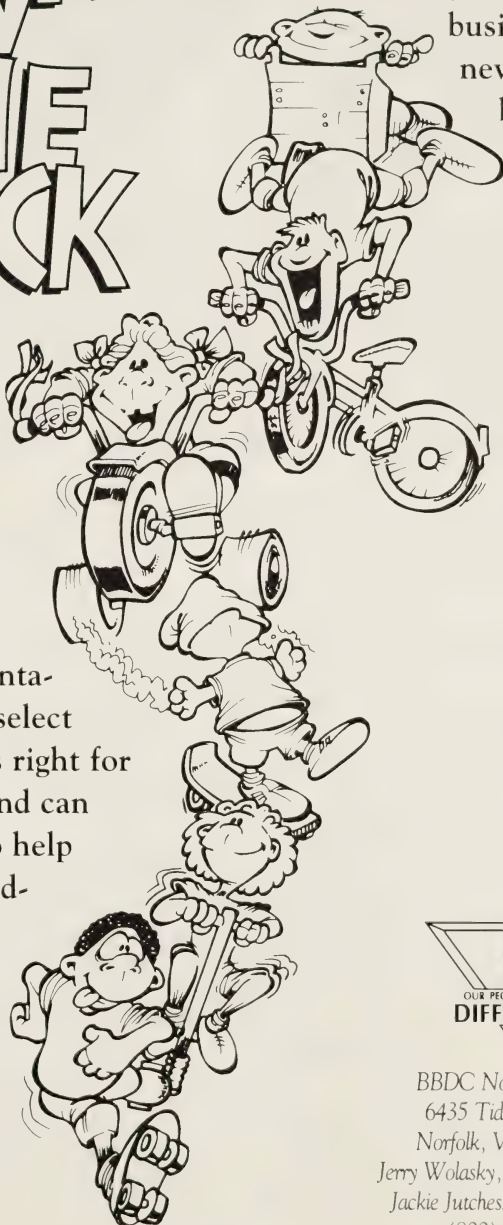
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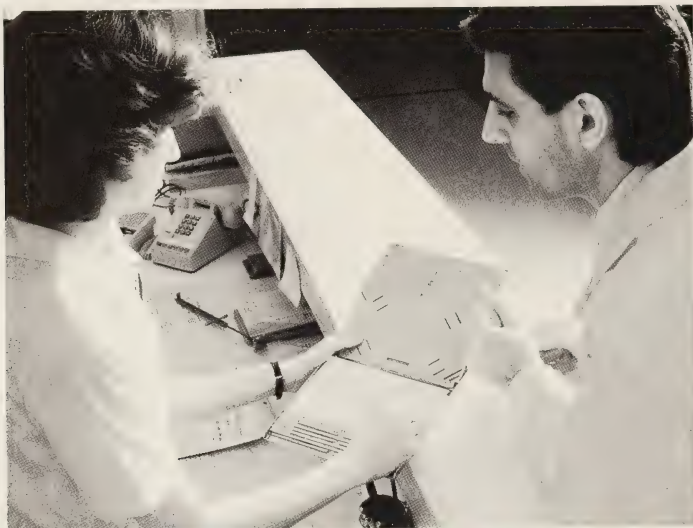
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# Patient Counseling Reduces Liability

David B. Brushwood, B.S.Pharm., J.D.

A very ordinary pharmacy malpractice case has taken on extraordinary significance for practicing pharmacists. The ordinary part is that the action claimed by the patient to be negligence was the simple misfilling of a prescription for Micronase with Maxzide. A routine dispensing error such as this one, tragic though it may be, is not normally the kind of thing that would warrant significant attention. What makes this otherwise common type of case unusual is that the judge who decided a preliminary motion in the case expressed the opinion that if the pharmacist had counseled the patient (about Maxzide) then the mistake would have been rectified and the harm to the patient would not have occurred (i.e., the patient would have said, "I thought I was getting medicine for diabetes").

The patient, thinking that the medicine she was taking was Micronase, followed her doctor's orders and took four Maxzide tablets daily. She became lethargic and unable to perform her daily functions. She started wondering whether she had been given the wrong medicine and she called the pharmacy. The pharmacist checked the records and discovered that the patient had indeed been given the wrong medication, and informed her of that.

The court examined the disclosure requirement for pharmacists. In reviewing the patient's legal claim, the court noted that whether one party (in this case a pharmacist) requires an examination of three factors: (1) the relationship of the parties, (2) the value of particular facts, and (3) the relative knowledge of each party.

Regarding the relationship between a pharmacist and a patient, the court commented as follows: "The relationship between a pharmacist and a client is one in which the client puts extreme trust in the pharmacist. This relationship of trust is reinforced by the esoteric nature of the pharmacist's profession. Pharmacists possess important specialized knowledge that is possessed by few, if any, non-pharmacists, and it is this specialized knowledge that puts patients in the position of having to put complete trust and confidence in a pharmacist's skill."

Based on this analysis, the court concluded that the relationship between a pharmacist and a patient is the type of relationship that would create a duty to disclose information. The court then turned to the value of the facts that would be disclosed, and commented as follows:

"In general, it is important that a person know the type of medicine the person is taking. For example, a person

may be allergic to a particular medicine, or a person may need to inform another doctor as to what medications the person is taking. Also, and this is another thing that patients depend on pharmacists to provide, a person needs to know the type of medicine he or she is taking so that the person can know what activities (i.e., drinking alcohol or dairy products) to avoid while taking the medication."

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highlight pharmacists and the law*

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The disclosure requirement described by the court is not overly burdensome. It does not require that every patient be told everything that is known about every drug. It requires simply that patients be told enough to enable them to use the medication the correct way. The court then spoke to the matter of the incorrect filling of the prescription being detected through patient counseling. The court said:

"In this specific case, it was important that Mrs. Griffin know the type of medicine she was taking because that information could have prevented Mrs. Griffin from suffering the effects of taking that drug instead of the drug that was prescribed."

Of course, if the pharmacist who dispensed Maxzide thought that he or she was dispensing Micronase, then the problem would not have been detected and rectified because the pharmacist would have incorrectly counseled about Micronase, just as he or she had incorrectly dispensed Micronase. However, if the pharmacist realized that he or she had dispensed Maxzide, then patient counseling about Maxzide would quickly have elicited a response from the patient indicating that she was expecting something for diabetes, not for blood pressure. Patient counseling (information disclosure as the court calls it) would not have guaranteed avoidance of the harm, but it would have reduced the probability of harm from a misfilled prescription.

The final factor, relative knowledge of the parties, was dealt with by the court through a description of the requirements placed on pharmacists for training and education, and the fact that licensure assures that only

*Continued on page 25....*

# Drug Information Questions

## Prevention of NSAID Induced Ulcers

Babette S. Prince, Pharm.D., Lillian Alade, R.Ph., UMAB Drug Information Center

This article provided under a grant-in-aid from **Glaxo**

### Drug Information Request

What alternatives are available for the prevention of ulcers in a patients using a non-steroidal anti-inflammatory drug (NSAID) chronically? How effective is misoprostol compared to the H<sub>2</sub> blockers?

### Response

Nonsteroidal anti-inflammatory drugs are widely used in the treatment of rheumatic diseases. On the average, greater than 1.2% of the entire US population use NSAIDs daily.<sup>1</sup> These drugs can cause gastroduodenal damage by two mechanisms: topical irritation and by a systemic effect that results in the reduction of tissue levels of prostaglandins via the inhibition of the activity of the cyclooxygenase enzyme system.<sup>2-4</sup>

Prostaglandins play a significant role in the defense of gastrointestinal mucosa.<sup>5</sup> The endogenous prostaglandins of the E series are believed to inhibit acid secretion, stimulate mucus production, increase bicarbonate output and maintain mucosal blood flow. Indirect inhibition of these activities by NSAIDs can result in complications such as ulcerations, bleeding and perforation.<sup>2,5,6</sup>

Ulcers caused by NSAIDs are most likely to occur in high risk patients such as the elderly (>60 years old), patients taking high doses of NSAIDs chronically, those with prior histories of peptic ulcers, smokers, heavy alcohol drinkers, and patients taking ulcerogenic or anticoagulant medications. Endoscopic exams of patients treated with NSAIDs show a preponderance of gastric over duodenal ulcers.<sup>1,2,7</sup> These ulcers often occur without antecedent or preceding symptoms.<sup>1</sup> Preventive therapy should therefore be considered in patients at high risk of developing NSAID-induced peptic ulcers.

The efficacy of a number of anti-ulcer drugs, in preventing NSAID-induced ulcers, has been evaluated in numerous studies.<sup>6,8-11</sup> The drugs that have been examined include misoprostol, H<sub>2</sub> blockers (cimetidine, ranitidine) and sucralfate. Although the aforementioned drugs and others such as omeprazole<sup>12</sup> and famotidine<sup>13</sup> have been evaluated for their usefulness in treatment, this article will focus on the prevention of NSAID-induced ulcerations.

Misoprostol (Cytotec<sup>®</sup>) is the only drug approved by the FDA for the prevention of NSAID-induced gastric ulcers in patients at high risk for complications. Misoprostol is an analogue of prostaglandin E<sub>1</sub> (PGE<sub>1</sub>), a natural prostaglandin that is abundant in the gastric mucosa. Misoprostol has been shown to have an antisecretory effect on gastric acid; however, it is believed to exert its actions via its ability to increase bicarbonate and mucous production.<sup>7,14</sup>

In a double-blind, placebo-controlled, multi-center trial by Graham et al<sup>8</sup>, 420 patients with osteoarthritis on various NSAIDs (ibuprofen, piroxicam and naproxen) were evaluated for the efficacy of misoprostol in preventing endoscopically documented gastric ulcers. The results showed that gastric ulcers occurred less frequently in patients who received either misoprostol 100 mcg or 200 mcg versus those who received placebo. Other studies have shown misoprostol (200 mcg qid) to be superior to placebo, cimetidine (300 mg qid) and sucralfate (1 gm qid) in the prevention or treatment of NSAID-induced gastric ulcers.<sup>8-10,14</sup>

In summary, misoprostol appears to be more effective in preventing gastric rather than duodenal ulcers in the above studies. Ranitidine, on the other hand, has not been shown to be effective in the prevention of gastric mucosal damage caused by NSAIDs.<sup>15</sup> The latter, however, is useful in reducing NSAID-induced damage to the duodenum.<sup>11,16</sup>

Diarrhea is the most frequently observed side effect of misoprostol.<sup>8,9,14</sup> In several trials, misoprostol has also been associated with abdominal pain or dyspepsia. Less common side effects include lethargy, nausea, vomiting, headache, flatulence, lightheadedness and gynecological disorders such as spotting and cramps. Misoprostol is contraindicated in pregnant women because of abortifacient properties that have been observed in animals. Women of childbearing capability considering therapy with misoprostol should be counselled on proper use of effective birth control while using the drug. The recommended dose of misoprostol is 200 mcg four times daily with food and at bedtime. If not tolerated, the manufacturer recommends a dose reduction to 100 mcg four times daily.<sup>14</sup> Misoprostol is priced comparably to H<sub>2</sub>

blockers.

Histamine-2 receptor ( $H_2$ ) blockers (cimetidine, ranitidine, famotidine, and nizatidine) have been shown to be effective in the treatment of NSAID-induced peptic ulcers but they appear to be less effective in prevention.<sup>7,17</sup> In general, they exert their anti-ulcer effects by blocking histamine receptors on parietal cells and thereby inhibiting the release of gastric acid via activation by cyclic AMP.<sup>17</sup>

In a double blind, placebo controlled study by Lanza et al<sup>9</sup>, the mucosal protection of misoprostol was compared to that of cimetidine in 90 normal volunteers that were receiving 400 mg tolmetin. Misoprostol was found to be superior in its protection of the gastric mucosa while cimetidine relieved pain much faster than misoprostol.<sup>9</sup> Robinson et al<sup>11</sup> evaluated the effect of ranitidine, compared with placebo, in preventing mucosal damage caused by NSAID use in 144 arthritis patients. This study was conducted for eight weeks. No duodenal ulcers occurred with ranitidine compared to 8% in the placebo group. There were no significant differences between the two treatment groups with respect to gastric ulcers. The results from another study by Ehsanullah et al<sup>16</sup> are consistent with these findings.

Adverse effects of  $H_2$  blockers include nausea, diarrhea, constipation, headache, drowsiness, fatigue and muscular pain.<sup>17</sup> Central nervous system (CNS) effects (such as mental confusion, agitation, hallucinations, delirium, irritability, obtundation and hostility) have also been associated with  $H_2$  blocker therapy. Cantu and Korek<sup>18</sup>, in a comprehensive review of the literature on CNS reactions to  $H_2$  receptor blockers found that central nervous system effects have been associated with all  $H_2$  blockers with an incidence of 1.6%-80% for hospitalized patients compared to <0.2% for outpatients. Even though there have been more reports associated with cimetidine, there is no evidence that one  $H_2$  agent is more likely to cause a CNS reaction than another. The only risk factor for CNS effects that could be supported by the medical literature was advanced age.<sup>4</sup>

Endocrine effects such as impotence, gynecomastia and galactorrhea have also been reported in patients on long term high doses of cimetidine.<sup>17</sup>  $H_2$  blockers in general interact with a number of drugs including theophylline, warfarin, phenytoin, lidocaine, propranolol and nifedipine by inhibiting the cytochrome P-450 liver enzyme system responsible for the metabolism of these drugs. The serum concentration levels and adverse effects of the interacting drugs may need to be monitored to avoid toxicity.

*Continued on page 26....*



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## Dickinson's Pharmacy

Jim Dickinson

### *Is PCS really pharmacy's friend?*

When Bob Johnson left the California Pharmacists Association two and a half years ago to become chief executive officer of McKesson's Pharmaceutical Card Systems (PCS), everyone was filled with optimism. I even wrote a column urging every pharmacist to support PCS.

Now I take that back. Bob's still doing a valiant job, trying to make hard-nosed, misinformed health plan administrators see what they don't want to see-- but the case of Lake Gregory pharmacy makes me want to withdraw my call for unqualified support of PCS, or any other claims processor/third party administrator, for that matter (let's keep this unemotional and objective).

PCS is probably better than most, but they all have to make a living in the same third-party jungle -- and that seems to mean sacrificing fair treatment of both pharmacies and patients.

Take the case of Lake Gregory Pharmacy, in the one-pharmacy mountain town of Crestline (pop. 8,000), California. Owner Ed Burrows thought that, with the nearest competing pharmacy 40 miles away, he could afford to be independent of fee-setting companies like PCS.

As long as he provided superior pharmacy services and excellent relationships with his patients, they would file paper claims for his charges and be paid in full. And until last May, that worked out fine.

Then one of his best patients showed him her reimbursement stub from PCS, where the claims processor had arbitrarily and without notice sliced 25% off her claim for his

\$209.95 charge for 60 Mevacor 40 mg tablets for a total reimbursement of \$159.46. This was \$3 below Ed's actual acquisition cost and \$39.63 below AWP.

Neither the patient nor he had been warned of this abrupt departure from previous PCS payment history for this drug and this patient (she had been receiving full payment for almost three years).

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***Would you pass up a million dollars just because a handful of fellow pharmacies might go under?***

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Ed called a RECAP pharmacist long-distance in Lake Arrowhead to compare experiences, and found that he had not been cut at all on Mevacor -- he had been direct-reimbursed \$204 for the same Rx.

Why the discrimination? Ed called me, and I called Bob Johnson, who seemed unsurprised at the discrimination but incredulous that PCS could have paid less than actual acquisition cost.

I faxed him Ed's proof -- a copy of his patient's reimbursement stub from PCS with Ed's handwritten notation of his actual acquisition cost and the Mevacor AWP.

After a week with no response to my fax -- more notice than PCS had provided Ed or his patient! -- I ran the story in my newsletter, under the headline "PCS cuts pharmacy to less than actual cost." That apparently energized PCS. In a few days, I got a peeved fax from Bob together with a

copy of an internal PCS memorandum responding to the newsletter story. The memo had been prepared by assistant vice president for professional services Dan Boesen, who, like Bob himself, had been recruited to PCS from pharmacy (formerly executive director of the Arizona Pharmacy Association and co-owner of two independent pharmacies).

Dan's memo said: "As is often the case, facts are discarded in favor of fictional anecdotes. Greg Watanabe reviewed our files and found that Lake Gregory Pharmacy in Crestline, California is not a RECAP pharmacy. The payment stub... is a patient claim stub and not the pharmacy claim stub.

"This plan actually pays full AWP. However, the patient's decision to use a non-participating pharmacy meant that the patient was reimbursed directly using a formula:

(Claim amount minus copay times 75%)

$\$209.95 - \$8.00 \times .75 = \$151.46$

"It would appear," Dan concluded, "that these facts were not considered prior to printing the newsletter and the pharmacist did not verify patient coverage prior to what appears to be his acceptance of assignment of payment."

In response, I tried to phone Bob but he was in travel. So I faxed him a letter describing the hardship PCS had caused Ed's patient. She faced a one-hour drive out of town to get her prescription filled at a RECAP pharmacy-- a perfect set-up for mail order.

PCS vice president Charlie Pulido faxed a short note in acknowledgement the next day: "PCS  
*Continued on page 25...*

## Dickinson's Pharmacy

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does not set these rules -- they are set by the plan sponsor. This plan sponsor requires a 25% penalty when non-network pharmacies are used."

I replied, in part: "PCS is the party that accepts or rejects plans that damage independent pharmacies, and it is the one that cuts the checks. It is also in a prime position to educate/counsel plan sponsors as to what will enhance their interests among providers; if PCS instead puts its own short-term interests first (a contract in the hand is worth two in the bush), it must take the PR consequences.

"I realize that the issue is RECAP versus no-RECAP; unfortunately, what should be a free option that succeeds or fails on its own merits in the open market becomes instead (at least in pharmacist's eyes) an economic bludgeon -- or as Lake Gregory Pharmacy's Ed Burrows puts it, 'tyranny.'

"PCS has been selling a difficult message to two skeptical audiences (pharmacies and plan sponsors), but it needs to do better than accept any plan with a 25% patient penalty for use of 'non-participating' pharmacies."

Admittedly, PCS and other claims processors have a tough row to hoe at times. The temptation must be great to put sponsor-education on the back burner when the prospect of winning a lucrative contract is at hand. Would you pass up, say, a million dollars just because a handful of "marginal" fellow pharmacists might go under and a few hundred patients forced to drive further to a pharmacy if you did?

And there, at press time, the matter lies. My question remains: Is PCS really pharmacy's friend? ■

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## Counseling Reduces Liability

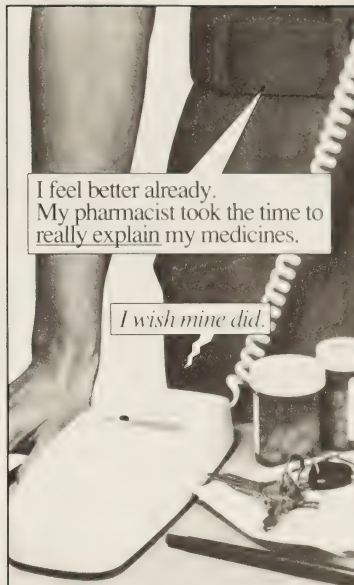
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pharmacists will dispense medications. The court concluded that "a patient wishing to fill a prescription is compelled to trust the skill and competence of a pharmacist because the patient cannot legally have the prescription filled by a non-pharmacist." Therefore, the pharmacist obviously has greater knowledge than the patient and that fact contributes to a duty to inform.

The court's final observation was that the existence of a duty to disclose depends on the particular facts and circumstances of each case. In other words, there is no duty to counsel patients under every set of facts, but only under certain sets of facts, where patients counseling would protect the patient from risk of harm. Assuring that the patient knows the name of the drug and the type of drug that he or she is receiving (i.e., antibiotic, anticoagulant, antihypertensive, etc.) is important for virtually every patient. But beyond that there is no absolute counseling requirement. The requirement only exists if facts support it.

This case is another in a growing list of cases that have found good reason for requiring that pharmacists inform patients about the characteristics of medications. It provides an incentive for pharmacists to slow down and counsel patients. Dispensing errors are inevitable because humans are fallible (machines are too), but the harm errors cause can be limited through patient counseling. ■

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## Drug Information Question

Continued from page 23....

Sucralfate is an aluminum hydroxide complex of sucrose. It is believed to have cytoprotective effects on the gastrointestinal mucosa.<sup>19,20</sup> However, a randomized, single-blind, multi-center, comparative study<sup>6</sup> in 253 osteoarthritis patient showed that sucralfate was less effective than misoprostol in the prevention of gastric ulcer in a three week long treatment course with NSAIDs. In other studies, however, sucralfate has been shown to be effective in preventing the formation of NSAID induced duodenal lesions.<sup>10</sup>

Omeprazole represents a class of compounds called the H<sup>+</sup>/K<sup>+</sup> ATPase pump inhibitors. It acts by blocking the transport of acid across the parietal cell membrane.<sup>17</sup> Omeprazole has been shown to cause anacidity (total acid inhibition) in normal volunteers with NSAID-induced gastroduodenal damage. A study by Daneshmend et al concluded that total inhibition of acid secretion will prevent bleeding and promote healing of NSAID-induced ulcers.<sup>12</sup> The long term use of omeprazole in rats has led to the development of gastric carcinoid tumors and increased gastrin levels in man. It is therefore unlikely that omeprazole will be used for the prevention of NSAID-induced ulcers in patients taking NSAIDs chronically.

There are several limitations to the studies available in the literature that examine alternatives for prevention of NSAID-induced peptic ulcers. Numerous studies utilized normal volunteers and so extrapolation had to be made to patients with rheumatic diseases. Secondly, the length of the studies, both in normal volunteers and in osteoarthritis patients, ranged from one week to a maximum of three months and so long term effects concerning morbidity and mortality are unknown. Thirdly, mucosal damage was not totally prevented.<sup>7</sup>

In lieu of these facts, the following guidelines are proposed for the prophylactic treatment of patients on chronic NSAID therapy:

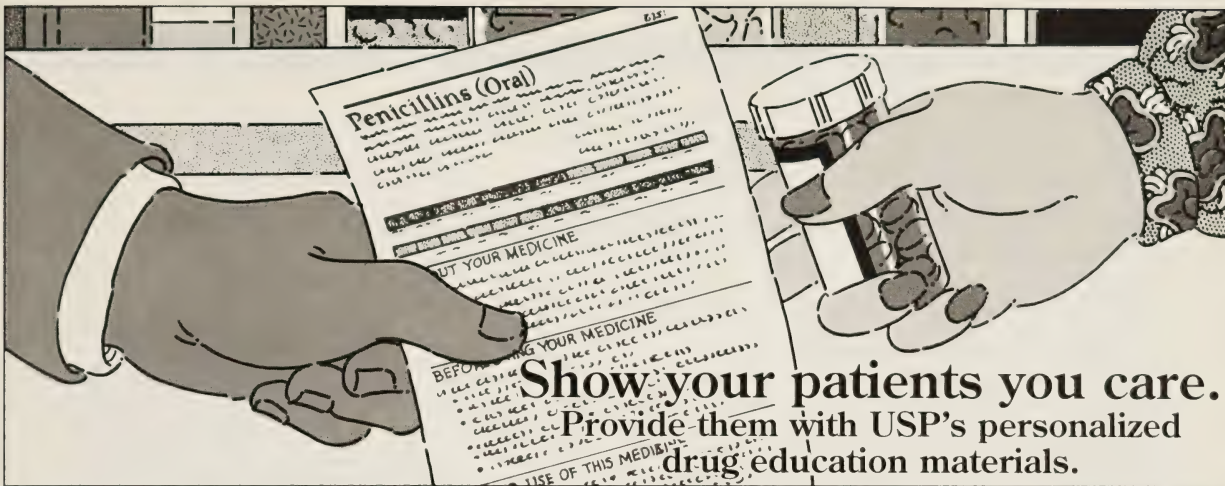
**Misoprostol 200 mcg qid** is the drug of choice for the prevention of NSAID induced gastropathy. This is also due to the fact that gastric ulcers occur more frequently than duodenal ulcers.

**Ranitidine 150 mg bid** should be considered in patients with a history of duodenal ulceration.

In conclusion, prophylactic treatment is not recommended in everyone. Until more studies in patients on chronic NSAIDs are done, the above guidelines will assist the pharmacist in making recommendations and thereby assist the physician in choosing rational drug therapy. ■

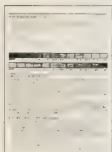
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## Access for the Disabled

### *The Implications of the Americans with Disabilities Act of 1990*

Wayne W. Oliver, J.D.

On July 26, 1992, President Bush signed into law the American with Disabilities Act of 1990. The purpose of the Act is to end discrimination against individuals with disabilities. The Act features two main provisions which affect pharmacy and pharmacists: hiring and employment practices (Title I) and ensuring the accessibility to handicapped patients and patrons (Title III).

The Americans with Disabilities Act of 1990 is crafted to bring over 43 million U.S. citizens into the socio-economic mainstream of American life. Some legal experts believe that the Act represents the most sweeping changes in the Civil Rights Act since 1965 when the Civil Rights Act was adopted.

#### What is a Disability?

Generally, the Act defines a "disability" as a physical or mental impairment that substantially limits one or more of a person's major life activities such as walking, talking, hearing, working, breathing, or caring for oneself on a daily and personal basis. Additionally, the Act specifies that the definition of disability includes the existence of a condition or record of such a physical or mental impairment. This expanded definition protects individuals who are recovering from a disability, for example, alcoholism, drug abuse or those who were initially misdiagnosed. Similarly, the Act is rather specific as to what does *not* constitute a "disability." The following conditions do not constitute a disability: homosexuality, bisexuality, transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, gender identity disorders not resulting from physical impairments, or other sexual behavior disorders; kleptomania, compulsive gambling, or pyromania, disorders resulting from illegal drug use; or other disorders which pose a direct threat to the health or safety of others in the work environment.

#### Employment Practices

Title I of the Americans with Disabilities Act specifically prohibits "discrimination against a qualified individual with a disability.... in regard to job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training and other terms, conditions, and privileges of employment." Additionally, the Act protects those individuals who must

provide care for disabled relatives or close friends.

Discriminatory behavior is delineated in the Act. Discrimination includes:

- limiting, segregating, or classifying a job applicant or employee in a manner which adversely affects that persons opportunity for advancement;
- denying employment to or the failure to make *reasonable accommodations* for the physical or mental disability of an otherwise qualified but disabled person.

A *qualified but disabled* person is someone who can "perform the essential functions of a job with or without reasonable accommodations." The essential functions of a job should be set forth in every job description.

Reasonable accommodations is subject to interpretation. It is generally viewed as making facilities more accessible, restructuring jobs, providing part-time work or adopting modified work schedules, (such as flexible hours, etc.). However, the reasonable accommodation requirement may be waived if an employer can show that making reasonable accommodations would cause undue hardship on the employer's business.

Title I of the Americans with Disabilities Act of 1990 became effect on July 26, 1992. Pharmacies and other businesses with 25 or more employees will be required to comply with the requirement of the Act. On July 26, 1994, pharmacies and other business with 15 or more employees will be covered by the Act.

#### Public Accommodations and Accessibility

While many community pharmacies will be exempt from the Title I provision of the Act because of the small number of employees (less than 25 after July 26, 1992 and less than 15 after July 26, 1994), all pharmacies must comply with the "Public Accommodation" requirements of the Act. The Public Accommodation provision became effective on January 1, 1992.

These provisions are designed to prohibit discrimination against disabled persons by denying the full and equal enjoyment of the goods and services, facilities, privileges and advantages of any public accommodation provided by private individuals or organizations. Among others, public accommodations include: pharmacies, grocery stores, physicians' offices, hotels, restaurants, museums, shopping

malls, and even homeless shelters.

Business facilities open to the public must remove barriers, if "readily achievable," has been defined as when only modest expenditures are required to remove barriers or the task can be easily accomplished. Some required changes may include the construction of ramps, the installation of offset hinges to accommodate wheelchairs and walkers, the addition of safety grab bars, and the lowering of telephones.

### ***How the ADA Affects Pharmacists***

#### ***Employment Practices***

- Hiring prospective employees
- Promoting present employees
- Discharging current employees

#### ***Making Your Pharmacy Accessible***

- Entry and exit doorways
- Sales and service counters
- Restrooms
- Telephones

#### ***Financial Incentives***

- Tax deduction up to \$30,000 for renovation
- Tax credit up to \$2,400 for hiring the disabled

Those business facilities undergoing major renovations are mandated to "be readily accessible to and usable by" the disabled. This includes incorporating and accessible travel area between the main area of business and the bathrooms, telephones, and drinking fountains. However, the cost of providing the accessible travel area need not be disproportionate to the cost of the overall renovation.

Any new building must also be designed and built to be readily accessible to and usable by disabled persons, unless "structurally impractical." This new building provision becomes effective on January 1, 1993.

Additionally, the Public Accommodation provisions of Title III

incorporate the issue of communication barriers. For example, some labor law experts have suggested that pharmacists must be prepared to read pertinent patient and prescription drug information to blind patients and similarly, be prepared to write instructions and other important information for deaf patients.

### **Enforcement of the Act**

The enforcement of Title I (employment practices) of the Americans with Disabilities Act of 1990 has been assigned to the Equal Employment Opportunity Commission (EEOC). It is expected that most of the investigations and subsequent claims will be generated

through a complaint by an applicant or employee. Upon investigation, the EEOC will either file suit on behalf of the claimant or issue a "Right to Sue Letter" to the claimant. Suits decided in favor of the claimant will result in relief awards such as hiring, reinstatement or promotion of the claimant. It is not anticipated that compensatory or punitive damages would be allowed under Title I violations.

The enforcement of Title III (public accommodation) of the Act rests with the U.S. Department of Justice and the Attorney General. Complaints regarding public access would be brought by private individuals or the Attorney General in civil court. Businesses found in violation of the Act could be subject to injunctions ordering compliance, monetary damages for the disabled, and fines up to \$100,000 for repeat offenders. Compensatory and punitive damages would be allowed under Title III suits.

### **Pharmacy Compliance**

Pharmacies and all small businesses should begin the process of planning to comply with the provisions of the Americans with Disabilities Act of 1990. In addition to the mandates of the Act, there are opportunities for community pharmacies, pharmacists and small business. Financial incentives are available to employers who hire the disabled. For example, employers will receive a tax credit of up to 40 percent of the first \$6,000 earned by a disabled person in the first year on the job. Financial incentives are also available for businesses who comply with the Title III provisions of the Act. Section 190 of the Internal Revenue Code allows businesses to deduct \$30,000 for the removal of architectural barriers.

### **Conclusion**

The Americans with Disabilities Act of 1990 offers disabled persons the opportunity to become integrated into the economic, social, and cultural fabric of America. Equally, there are opportunities for community pharmacies and pharmacists. Disabled employees have the highest rate of attendance, the highest rate of employer satisfactions. The benefits to community pharmacies are numerous: stable employees, financial incentives for hiring the disabled and for making the pharmacy more accessible to the disabled and increased financial rewards from increased spending by the disabled. ■

Wayne W. Oliver, J.D., is vice president for Professional Relations and Government Affairs for the Georgia Pharmaceutical Association. This article is reprinted, with permission, from the *Georgia Pharmaceutical Journal*, December 1991.

# Continuing Education

## Continuing Education Quiz

September 1992 -- Patient Counseling

Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by March 31, 1993. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

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Is this program used to meet your mandatory CE requirements?  
Was this issue/article useful to you in your practice?

☐ Yes      ☐ No  
☐ Yes      ☐ No

d. suggestive

1. Maryland's patient counseling law went/goes into effect on:

- a. July 1, 1992
- b. October 1, 1992
- c. January 1, 1993
- d. July 1, 1993

2. Which of the following combinations would satisfy the patient counseling law's "offer to counsel" requirement?

- a. a poster and a bag stuffer
- b. a poster and having a technician ask the patient if they need counseling
- c. a telephone call from the pharmacist and a bag stuffer
- d. a and c only
- e. b and c only

3. The Maryland patient counseling law applies to:

- a. all patients, all prescriptions
- b. all Medicaid recipients, all prescriptions
- c. all patients, new prescriptions
- d. all Medicaid recipients, new prescriptions

4. In a pharmacist-patient encounter, the strongest impression or message is reportedly conveyed by the:

- a. pharmacist's body language
- b. pharmacist's tone and facial expression
- c. physical layout of the pharmacy
- d. wording of the directions

5. Which of the following questioning techniques best describes the question "Are you following your doctor's directions?"

- a. close ended
- b. open-ended
- c. direct

6. Long term, high dose use of cimetidine can lead to:

- a. gynecomastia and impotence
- b. alopecia and fine muscle tremors
- c. galatorrhea and cirrhosis
- d. b and c

7. In *Griffin vs. Phar-Mor*, the courts found that the pharmacist's dispensing error could have been caught:

- a. if the pharmacist had phoned the prescriber
- b. if the pharmacist had counseled the patient
- c. if the patient had read the directions carefully
- d. if the prescriber had phoned the patient

8. OBRA '90 required:

- a. manufacturer rebates to Medicaid programs
- b. drug utilization review (DUR)
- c. patient counseling of Medicaid recipients
- d. all of the above

9. The 1975 Millis Report stated that pharmacists of the future will be:

- a. largely replaced by computers
- b. more concerned with dispensing accuracy
- c. primarily female
- d. transmitters of information

10. "Talk About Prescriptions" Month, sponsored by the National Council on Patient Information and Education,

- a. is held every January and June
- b. is held every October
- c. will be held for the first time this year
- d. is underwritten by the AMA

# Classified

**THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION**, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Kateoff at (410) 358-7036.

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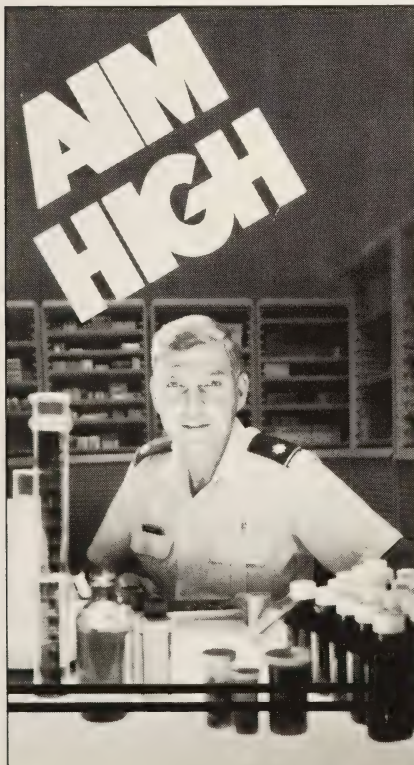
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# Help Make A Difference



Promote pharmacy and your profession by helping the Maryland Pharmacists Association publicize "Talk About Prescriptions" Month in October by volunteering! MPhA, in cooperation with the Department on Aging, the Department of Human Resources, the Department of Health and Mental Hygiene and the University of Maryland School of Pharmacy will be launching new programs designed to increase consumer awareness of their medications. Of greatest importance to your Association is the opportunity to raise consumer's understanding of what their pharmacist can do for them.....

Here's what we have planned

## September 30, 1992

### Senior Assisted Housing Visits

Kirkwood House, Baltimore, Maryland

9:00 am - 5:00 pm

MPhA needs at least ten pharmacists to meet with individual residents of the Kirkwood House Senior Development. Each pharmacist will meet, review and discuss medication use with up to eight residents. This event will be attended by Governor Schaefer and the local media.

## October 15, 1992

### Brown Bag Medication Program For Maryland State Employees

201 West Preston Street, Baltimore, Maryland

9:00 am - 5:00 pm

MPhA needs at least ten pharmacists to help promote good medication use and compliance by state employees. You will be needed to review the patient's prescription and over-the-counter history with them and answer their questions about the medications. MPhA will provide a complimentary copy of USP's *About Your Medicines* to each state employee. Pharmacists will need to provide their own reference materials.

*To volunteer or for questions, call MPhA at (800) 833-7587.*

# The Maryland Pharmacist

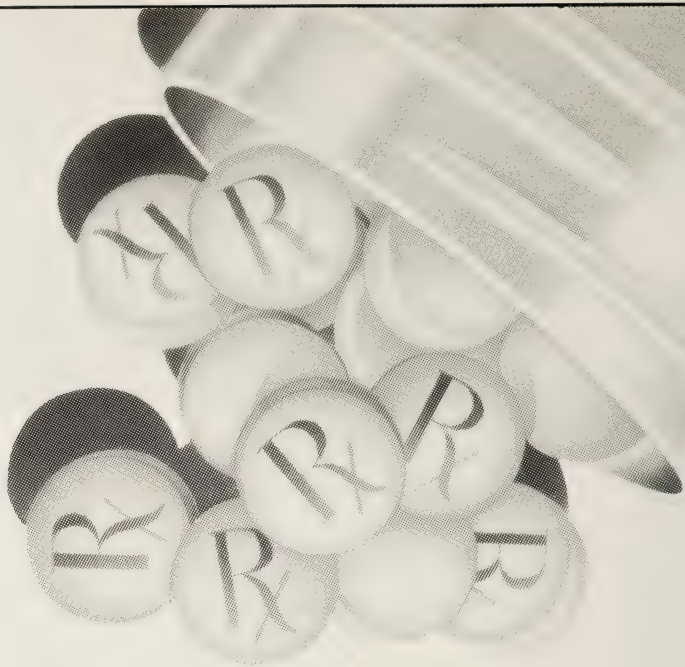
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*Taking a Closer Look*



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# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association  
650 West Lombard Street, Baltimore, Maryland 21201-1572

October 1992

Volume 68

Number 10

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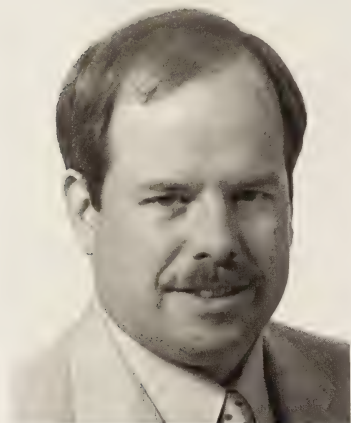
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## Guest Commentary

*Kenneth Whittemore, Jr., P.D., President, Mid-Atlantic DUR, Inc.*



### ***Not "win-win," but "win-win-win-win-win!"***

Much has been made of the "win-win" situation in business, psychological and other circles over the past few years. Such situations represent that wonderful state in which both parties to an agreement realize a positive benefit. As difficult as it can be to achieve the win-win goal, imagine how unlikely it is that five parties might benefit from one development. Yet, this is exactly what has happened in the seven years since the MPhA made the choice to delve into the emerging specialty known as drug utilization review.

It was around 1985 when MPhA's former Executive Director Dave Banta heard a presentation Lee Morse made to a meeting of state pharmacy association executives. In the presentation, Mr. Morse introduced them to the idea of drug utilization review. Realizing that involvement in DUR made sense both professionally and economically for MPhA, Dave set the development process in motion. Within two years, MPhA was in the DUR business.

The first contract to provide DUR services was awarded to MPhA by Maryland Medicaid in 1986. Before the year was out, the first profiles were produced and reviewed by panels of pharmacists and physicians; the first DUR letters were mailed to providers shortly thereafter. In 1989, in a move which demonstrated the true value of DUR, Maryland Medicaid renewed its contract with MPhA for a second three-year period. It was clear that MPhA was on the right track.

The next major milestone in MPhA's DUR history came in 1990 when Maryland Blue Cross/Blue Shield awarded a one-year contract to MPhA to provide DUR services for the Maryland State Employees Prescription Drug Benefit Program. With this award, MPhA became one of the first providers of DUR to service both the public and private sectors.

Now, in 1992, another major milestone has been reached. In July, MPhA split its DUR operation off into a separate, for-profit subsidiary -- Mid-Atlantic DUR, Inc. It is a free-standing company with its own directors and officers. Mid-Atlantic now provides DUR services covering over 650,000 lives, or approximately 14 percent of the population of Maryland. The company is a leader in the field of retrospective drug utilization review services.

So, who wins with Mid-Atlantic DUR, Inc.? A partial list includes:

- *The citizens of Maryland* -- because many of them now benefit from safer, more appropriate drug therapy.
- *Maryland's tax payers* -- because the excess costs associated with unsound prescribing and dispensing habits are now being reduced for state-funded prescription programs.
- *The profession of pharmacy* -- because the role that pharmacists can play in promoting the rational use of medicines is now being recognized.
- *The MPhA* -- because the association is now widely regarded as a leader among its peer organizations for its strategic vision.

- *The members of the MPhA -- because Mid-Atlantic provides the association with significant non-dues income which has helped keep dues low, even as services have increased.*

Yes, Mid-Atlantic DUR, Inc. truly represents a win-win-win-win-win situation. It is an achievement with which every member of the MPhA can be proud!

DUR is now on the mind of every pharmacist in the United States. January 1, 1993 represents another milestone for the profession -- the implementation date for the DUR provisions of OBRA '90. Soon, all pharmacists will be concerned with not just retrospective DUR, but also prospective and concurrent DUR. It was with this in mind that this month's journal was written. We hope that you find it to be useful as you prepare for the demands of the new year.

In closing, I would like to recognize the efforts of three important individuals -- MPhA's DUR past and present DUR directors: Jean Hoffman, David Miller and Richard Baylis. These people are the primary reason that this effort has been so successful for Maryland pharmacy. Without their hard work, it is doubtful that Mid-Atlantic DUR would be in existence today. Our thanks to all of you. And to Richard, keep up the good work! ■

## *A Few Accomplishments*

MPhA's retrospective drug utilization review program is much, much more than just educational letters about drug problems to prescribers and pharmacists. Here's just a sample of our activities since the beginning of this year.

### **January**

After several years of research and examination by Mid-Atlantic DUR, Maryland Medicaid implements a special program for the prescribing of H<sub>2</sub> antagonists. The program is designed to encourage appropriate utilization of this drug class and reduce costs to the program.

Mid-Atlantic DUR, Inc. develops patient and provider tracking criteria for the use of temazepam, flurazepam and triazolam. Any Medicaid recipient receiving four or more prescriptions of any of the three drugs within the last eight month period are reviewed. 1,109 cases of inappropriate use are uncovered and result in 2,223 educational intervention letters to providers.

### **March**

Following up on the program's efforts in January, Maryland Medicaid sends letters to nursing homes requesting justification for continued resident use of sedative/hypnotics in long term care facilities. Supplementing Mid-Atlantic DUR's information, Medicaid includes HCFA hypnotic regulations for drug use in nursing homes.

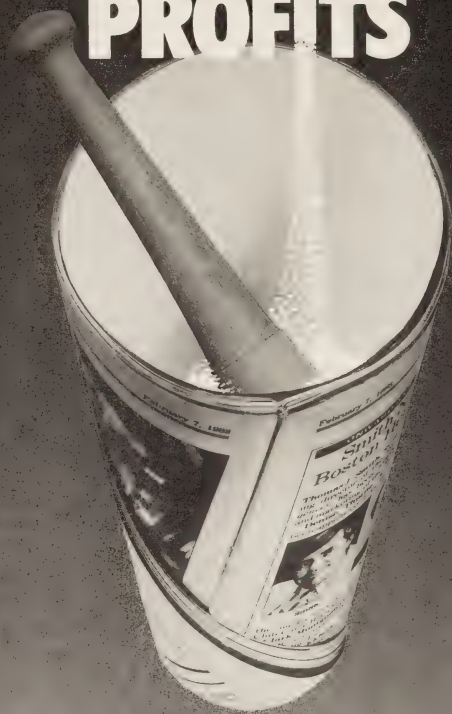
DUR, in conjunction with the University of Maryland School of Pharmacy's Clinical Pharmacy Department, institutes a monthly educational presentation at the University Hospital for residents and staff physicians. The program concentrates on prescribing problems identified by the DUR program in Maryland. Plans made to expand this to Johns Hopkins Medical School within by 1993.

MPhA is awarded a \$9,800 grant from the National Council on State Pharmaceutical Association Executives and The Upjohn Company to develop an educational video-tape and instruction booklet for training pharmacists and physicians in retrospective therapeutic drug utilization review.

### **April**

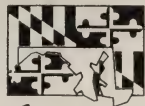
Mid-Atlantic DUR conducts a round table discussion about sleep disorders led by three Baltimore physicians specializing in this field. The target audience are prescribers identified in the January study of sedative/hypnotics.

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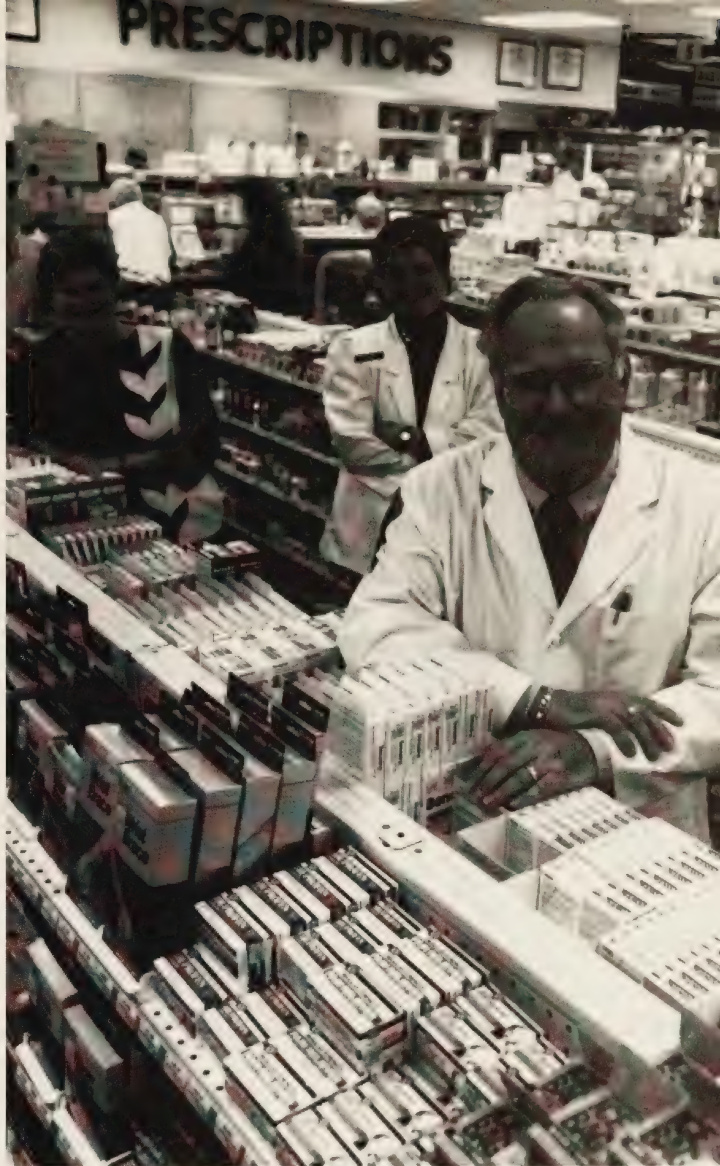
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*Norman F. Beyer, of Butler Pharmacy in Point Pleasant, New Jersey with his daughters, Leslie B. Bugg and Tracie B. Steel.*



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# Retrospective Drug Utilization Review

## *How the Mid-Atlantic DUR Program Works*

*Richard D. Baylis, P.D., F.A.S.C.P., Director, DUR Services*



OBRA '90 had lasting effects on the pharmacy profession -- manufacturer rebates for Medicaid, a moratorium on lower Medicaid reimbursement, mandatory patient counseling, and a requirement for prospective and retrospective drug utilization review. Maryland Medicaid, through the Maryland Pharmacists Association and now its for-profit subsidiary Mid-Atlantic DUR, Inc., has had an operational therapeutic drug utilization review program for more than six years. The cooperation of Maryland pharmacists has been instrumental in making our program a national model. This article will walk you through the step-by-step process of retrospective DUR.

Claims submitted by providers to an insurer's benefit administrator/claims processor are entered into a centralized claim management system. These prescription claims comprise the medical information data base from which patient history profiles are generated. Medical history files on each patient comprise approximately six to eighteen months of information.

Each month, the patient profile data base is updated with the most current batches of paid pharmacy claims. Profiles are updated at the same time for patients already in the data base and new profiles are created for new subscribers entering the benefit system.

After the monthly update from the cumulative pharmacy claim submissions has been finished, therapeutically oriented drug and disease criteria are then used to generate the hard-copy profiles to be reviewed by DUR professional reviewers. The Maryland DUR program's multidisciplinary Therapeutic Review Criteria Committee (TRCC) reviews, develops, and approves the therapeutic criteria used to select the drug history profiles for review. The TRCC reviews "high risk" drug groupings, drug use characteristics, and disease/diagnosis classifications that present the greatest potential for *all* drug therapy related problems in Maryland.

The hard-copy of a potential "high risk" profile does not preclude the possibility that the drug therapy identified is medically and therapeutically appropriate. Only those history profiles that exhibit clinically relevant risks for possible drug therapy induced illness will warrant a committee inquiry.

Computer screened and printed "high risk" profiles are then sent to the DUR office. Profiles are divided evenly and mailed to 25 physician and pharmacy reviewers serving on the program's five regional committees. Of course, reviewers are required to handle and store patient drug history profiles with the strictest level of confidentiality. Both the profiles and the proceedings of the DUR committee are kept confidential.

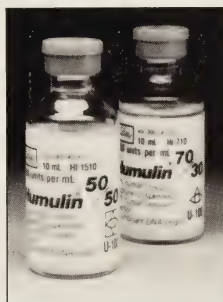
Each of the five DUR Committees meets monthly. At these meetings, the reviewers present their profiles and give their recommendations on whether or not the program should contact the prescriber(s) and dispenser(s) involved in the patient's care. The Committee functions as a sounding board -- allowing reviewers with different areas of expertise to present various perspectives on the clinical significance of potential problems discovered in the profile.



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When reviewing profiles or participating in Committee discussions, the clinical reviewers look for problems in the following five major areas.

### **Iatrogenic and Adverse Drug Reactions**

Iatrogenic problems are most often associated with the extended use of a drug therapy with a potential for secondary complications. Adverse drug reactions generally occur within a short period after initiation of drug therapy and thus, are difficult to prevent via DUR. However, the DUR program has found that communications with prescriber and pharmacy providers may prevent future problems in other patients. Both prescribers and pharmacists associated with drug therapy patterns exhibiting a potential for iatrogenic complications or adverse reactions should be provided with a copy of the drug profile and a letter identifying the potential hazard. Committee members review each profile to determine the most significant therapeutic problem to the patient. If a problem is discovered, the reviewer identifies the appropriate type of letter and to which providers such correspondence should be mailed. At the committee meeting, the reviewer presents the case and other reviewers discuss the patient's problem. Discussion at meetings can often uncover problems that one reviewer may have missed, thereby improving the quality of information ultimately sent to the provider.

### **Overutilization**

Drug therapy patterns exhibiting possible overutilization should be shared with all prescribers and pharmacist associated with the questionable therapy. Overutilization is determined from the "high risk" profile's date of service and days supply fields. When the overutilization is characterized by duplication of therapy involving multiple prescribers and/or pharmacists, referral to the insurer should be considered.

### **Underutilization**

Often underutilization represents a problem of patient compliance or patient understanding of the medication's purpose or dosage schedule. Patients -- particularly those

on chronic or maintenance therapies -- will generally have contact with their pharmacist more frequently than with their primary care prescribers. Therefore, pharmacists may have a greater opportunity than prescribers to discuss and resolve these types of problems. Inquires regarding poor patient compliance or underutilization can be determined by the profile's date of service and days supply fields also. Informational copies of these communications forwarded to the appropriate prescriber(s).

### **Contraindicated Drug Combinations**

Drug therapy patterns characterized by the use of contraindicated drug combinations should be shared with both the prescriber(s) and pharmacist(s) involved. Contraindicated drug combinations appear to be often associated with patients who are being treated with multiple prescribers. It is recommended that committee inquiries and profiles regarding multiple prescribers-treated patients be addressed to both current providers, as well as past providers. Patients whose drug combinations exhibit an abuse situation should be referred to the insurer's contact.

### **Drug Therapy Contraindicated by Diagnosis**

Patients are typically poor personal medical historians. Consequently, newly initiated drug therapies may occasionally be contraindicated by an already existing patient condition. These situations are particularly apparent among patients treated by multiple prescribers. Drug therapy patterns exhibiting this type of problem should be shared with all prescribers associated with the patients care. Pharmacists should also receive informational copies of these correspondences along with the patient's profile

### **Correspondence with Providers**

Letters to providers addressing the problems uncovered by the computer screenings and the clinical reviewer recommendations are then created and mailed by the DUR office. Each letter is accompanied by a response form and return envelope to enhance two-way

### **About Those DUR Letters**

You just finished hanging on the phone for 15 minutes on "ignore"; the driver called -- he ran out of gas; and five patients are waiting for their prescriptions to be filled ( 3 Medicaid and 2 Blue Cross). The mail arrives and there IT is - a letter from DUR!

You think, "What's the \*&#%)( is this? Don't I have enough paper work without some bureaucracy adding more. This is the doctor's responsibility, not mine!"

First, the letter is not a condemnation on how you practice your profession. The letter is intended to alert you to a potential therapeutic problem for one of the patients under your care.

Second, the intent of the letter is to encourage you to communicate with the patient and/or the prescriber about the potential problem. This inter-professional communication can enhance the quality of care delivered to the patient and prevent additional medical and pharmacy costs by keeping the patient healthy.

The success of a well run drug utilization review program is based on communication between the participants. The provider feed-back the program receives reinforces the outcomes we observe.

Therefore, it is very important to return the response form with comments to the program. Only through pharmacist support can Mid-Atlantic DUR demonstrate to third-party administrators that the pharmacy profession is making an impact on patient care. ●

communication between the provider, the DUR office, and the review committees.

Once a provider responds to a DUR letter, the DUR office evaluates each inquiry response to determine whether: additional information that clarifies the suspected drug therapy problem has been provided; or, a remedial action that will resolve the drug therapy problem has been proposed. Summaries of these inquiry responses

are prepared by the DUR director on a monthly basis and presented to the DUR committee. A brief review of the circumstances precipitating the inquiry prefaces summarized responses.

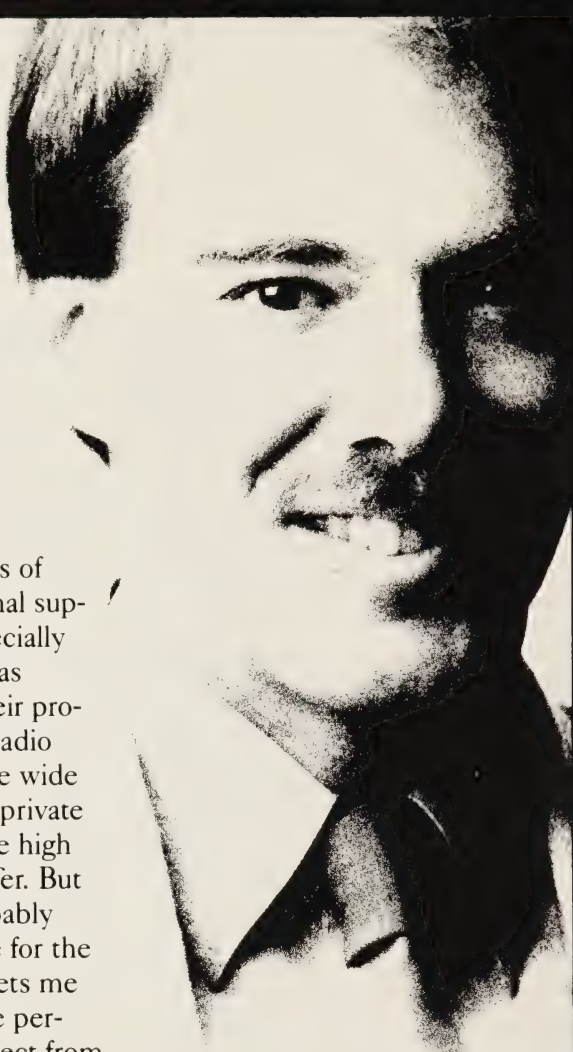
A case will be considered closed by recommendation of the DUR committee when additional medication information which clarifies the drug therapy under question has been provided to the committees. Case inquiries in which the response received is deemed unsatisfactory by the committee, will remain open and the DUR director will address a follow-up communication to the appropriate providers.

This is a quality control component of DUR programs. It is through this activity that verification of an improvement in a patient's drug therapy regimen can be made. Re-review status automatically calls for the regeneration of the patient drug history profile 180 days after initial contact with the provider(s). Failure of the follow-up patient drug profile to exhibit the remedial action proposed by the queried provider(s) will begin the intervention cycle again--provider contact, requested response, and subsequent follow-up review. Profiles exhibiting desired changes in the area of initial concern will be placed on Closed Status.

It must be recognized that providers are under no obligation to respond to a DUR inquiry. A provider may take remedial action on a drug therapy problem without responding in writing to the DUR office. Therefore, all cases in which a provider does not respond are automatically placed on re-reviewed status for follow-up in 180 days post initial contact.

On a monthly basis, the DUR office is responsible for creating administrative statistical reports outlining the number of profiles generated, profiles reviewed new cases identified, quantities of letters sent to providers, responses received from the previous months's correspondence, cases closed and follow-ups sent.

Additionally, the DUR office tracks and reports on the qualitative analysis report is generated every six months. On an annual basis, both quantitative and qualitative reports are compiled together along with risk-reduction calculations, average dollar saved per case on prescription expenditures, and an estimated reduction in remedial health care services do to drug induced illness. ■



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be a reason.**

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*Scott Rickards*

**SCOTT RICKARDS**  
RICKSAVE DRUG  
NAPLES, MAINE

**McKesson**

# The OBRA 1987 Regulations

## *Drug Regimen Reviews in Long Term Care Facilities*

*Peter P. Lamy, Ph.D., Sc.D., Madeline Feinberg, B.S.Pharm., Marvin L. Oed, B.S. Pharm.*

In 1974, the standards governing long-term care facilities were revised. Pharmacists were charged with the responsibility for drug regimen review (DRR) of each resident's drug therapy at least monthly, reporting any irregularities to the facility's medical director and administrator.

DRR is defined as the systematic evaluation of medication therapy viewed within the context of patient-specific data. The focus of DRR is always on the individual patient (rather than on aggregate usage patterns). DRR is required in nursing facilities by federal law as a condition of participation for both Medicare and Medicaid. DRR was found to be effective in a report by the Comptroller General in 1986.

### ***OBRA '87 regulations constitute the first time that prescription use be justified***

The Omnibus Budget Reconciliation Act of 1987 (OBRA 1987) revised extensively the Medicare and Medicaid requirements for long-term care institutions. Regulations were promulgated that incorporated these requirements and they became effective in October 1991. These regulations constitute the first time that prescription drugs are required, by law, to be justified by indication documented in the medical chart.

The section on antipsychotics, for example, consists of four components:

(a) documentation of a specific condition, including psychiatric diagnoses that warrant neuroleptic use; (b) prohibition of neuroleptics if certain behaviors are the only justification; (c) prohibition of neuroleptic use on an as-needed bases, and (d) gradual dose reduction coupled with attempts at behavioral programming, including environmental modification. In short, the regulations of OBRA 1987 seek to modify problem behavior of physicians. OBRA rules prohibit aversive therapy or punishment to modify problem behaviors of patients. The regulations seem to have had a beneficial effect, apparently reducing the use of neuroleptics by more than 60% from October to November, i.e. the first month that the regulations were in effect.

It is important to note that a number of other regulations followed. Under OBRA 1990, states will have the option of including home care patients (elderly and disabled) under Medicaid and OBRA 1987 regulations would then apply to this sector, too. In order to meet federal requirements of OBRA 1990, states will be required to provide a drug utilization review process. Pharmacists then will have to give the information listed in Table I to patients and caregivers.

The latest regulations (Omnibus Nursing Home Requirements) seek to control drug use even more stringently. Under these proposed regulations, psychopharmacologic drugs would be defined as "any drug prescribed with the intent of controlling mood, mental status, or

### **Information that Pharmacists Will Give to Patients and Caregivers**

*Mandated under OBRA 1990*

- Name and description of medication
- Route, dosage form, duration of therapy
- Special directions and precautions
- Common severe side effects, interactions, and therapeutic contraindications
- Techniques for self-monitoring of drug therapy
- Proper storage information
- Prescription refill information
- Action to be taken if dose is missed

behavior". Thus, the definition includes any drug so prescribed, "regardless of the manner in which it is marketed by the manufacturer and regardless of labeling to other approvals by FDA". HCFA can then, for example, regulate the use of antihistamines which can have a sedative effect.

Importantly, it is proposed that before a psychopharmacologic drug can be used in a non-emergency situation, "the facility must explain the use of the drug, explain the resident's

right to refuse the drug, and obtain written consent for the use of drug" none of which, incidentally, would relieve the facility in any way of its responsibility.

Finally, the new regulations state that "the physician is free to prescribe chemical restraints if such drug use is necessary in any emergency to ensure the physical safety of the resident or other resident" and if such drug use is not for discipline or convenience.

Overuse of psychotropic agents has been well documented, as has been the underuse of drugs to treat depression. Antipsychotics have been used inappropriately for controlling behavioral problems, and antidepressants are still too often used as the only approach to situational depression. Federal regulations mandate that state Medicaid programs implement, by 1993, DUE programs which specifically intervene on inappropriate or nonconforming prescribing (OBRA 1990).

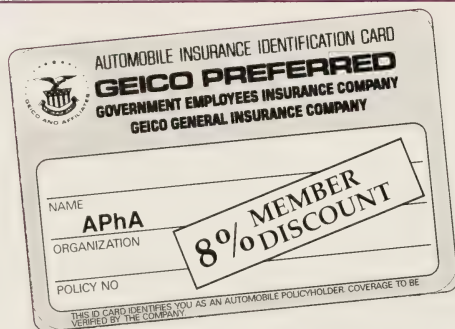
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## About the Authors

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# Resident Assessment Protocol

## *Delirium*

### **I. Problem**

Delirium (acute confusional state) is a common indicator or nonspecific symptom of a variety of acute, treatable illnesses. It is a serious problem, with high rates of morbidity and mortality, unless it is recognized and treated appropriately. Delirium is never a part of normal aging. Some of the classic signs of delirium may be difficult to recognize and may be mistaken for the natural progression of dementia, particularly in the late states of dementia when delirium has high mortality. Thus careful observation of the resident and review of potential causes are essential.

Delirium is characterized by fluctuating states of consciousness, disorientation, decreased environmental awareness, and behavioral changes. The onset of delirium may vary, depending on the severity of the cause(s) and the resident's health status; however, it usually develops rapidly, over a few days or even hours. Even with successful treatment of cause(s) and associated symptoms, it may take several weeks before cognitive abilities return to pre-delirium status.

Successful management depends on accurate identification of the clinical picture, correct diagnosis of specific cause(s), and prompt nursing and medical intervention. Delirium is often caused and aggravated by multiple factors. Thus, if you identify and address one cause, but delirium continues, you should continue to review the other major causes of delirium and treat any that are found.

### **II. Triggers**

A delirium problem could exist if there is any indication of:

1. any indicator of disordered thinking
2. cognitive/communication/behavior decline
3. mood decline and any of following: motor agitation, withdrawal, or hallucinations/delusions.
4. alcohol withdrawal, drug-induced, acute or subacute delirium

### **III. Guidelines**

Detecting signs and symptoms of delirium requires careful observation. Knowledge of a person's baseline cognitive abilities facilitates evaluation

Staff should become familiar with residents' cognitive function by regularly observing the resident in a variety of situations so that even subtle but important changes can be recognized.

When observed in this manner, the presence of any trigger signs or symptoms may be seen as a potential marker for acute, treatable illness.

An approach to detection and treatment of the problem can be selected by reviewing the items that follow in the order presented.

### **IV. Diagnoses and Conditions**

By correctly identifying the underlying cause(s) of delirium, you may prevent a cycle of worsening symptoms (e.g., an infection-fever-dehydration-confusion syndrome) or a drug regimen for a suspected cause that worsens the condition. The most common causes of delirium are associated with circulatory, respiratory, infectious, and metabolic disorders. However, finding one cause or disorder does not rule out the possibility of additional causes or multiple interrelated factors.

### **Medications**

Many medications given alone or in combination can cause delirium. If necessary, check doctors order against med sheet and drug labels to avoid the common problem of medication error.

Drugs that cause delirium:

1. Psychotropics including antipsychotics, anti-anxiety agents, hypnotics, and antidepressants.
2. Cardiac agents including: digitalis glycosides; antiarrhythmics; such as quinidine, procainamide, disopyramide; calcium channel blockers, such as verapamil, nifedipine, and diltiazem; antihypertensives, such as methyldopa, propranolol.
3. Gastrointestinal agents including: H<sub>2</sub> antagonists such as cimetidine and ranitidine.

4. Analgesics such as propoxyphene, narcotics.
5. Anti-inflammatory agents including: corticosteroids such as prednisone; NSAIDs such as ibuprofen.
6. OTC Products, especially those with anticholinergic properties, including: cold remedies (antihistamines, pseudoephedrine); sedatives (antihistamines, pseudoephedrine); stay-awakes (caffeine); antinauseants; alcohol.
- 1) Review the resident's drug profile with a physician.
- 2) Review all medications (regularly prescribed, PRN, and "over-the-counter" drugs).
- 3) Number of medications. The greater the number, the greater the possibility of adverse drug reaction/toxicity.
- 4) Review medications to determine need and benefit (ask if resident is receiving more than one drug class to treat a condition).
- 5) Check to determine whether nonpharmacological interventions have been considered (e.g., a behavior management program rather than antipsychotics to address the needs of a resident who is physically or verbally abusive).

#### *New Medications*

- 1) Review to determine whether there is a temporal relationship between onset or worsening of delirium and start of new medication.

### **Psychosocial**

After serious illness and drug toxicity are ruled out as cause of delirium, consider the possibility that the resident is experiencing psychosocial distress that may produce signs of delirium.

#### *Isolation*

- 1) Has the resident been away from people, objects and situations?
- 2) Is resident confused about time, place and meaning?
- 3) Has the resident been in bed or in an isolated area while recuperating from an illness or receiving a treatment?
- 4) Review the MDS to determine whether the resident has experienced a recent loss of a close family member or friend. Loss of someone close can precipitate a grief reaction that presents as acute confusion, especially if the person provided safety and structure for a demented resident.
- 5) Is the resident depressed, sad or anxious? Mood states can lead to confusional states that resolve with appropriated treatment. Review the MDS to determine whether the resident exhibits any signs or symptoms of sad or anxious mood or has a diagnosis of a psychiatric illness
- 6) Is the resident restrained? Restraints often aggravate the conditions staff are trying to treat (e.g. confusion, agitation, wandering). Did the resident become more agitated and confused with their use?

#### *Recent relocation*

- 1) Has the resident been admitted to a new environment (new room, unit, facility)?
- 2) Was there an orientation program that provided a calm, gentle approach with reminders and structure to help the resident settle into the environment?

### **Sensory Losses**

Sensory impairments often produce signs of confusion and disorientation, as well as behavior changes. This is especially true of residents with early signs of dementia. They can also aggravate a confusional state by impairing the resident's ability to accurately perceive or cope with environmental stimuli (e.g. loud noises, onset of evening). This can lead to the resident experiencing hallucinations or delusions and misinterpreting noises and images.

#### *Hearing*

- 1) Is hearing deficit related to easily remedied situations -- impacted ear wax or hearing aid dysfunction?
- 2) Has sensory deprivation led to confusion?
- 3) Has physician input been sought?

#### *Vision*

- 1) Has vision loss created sensory deprivation resulting in confusion?
- 2) Have major changes occurred in visual function without the resident's being referred to a physician?



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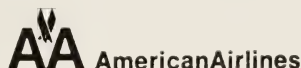
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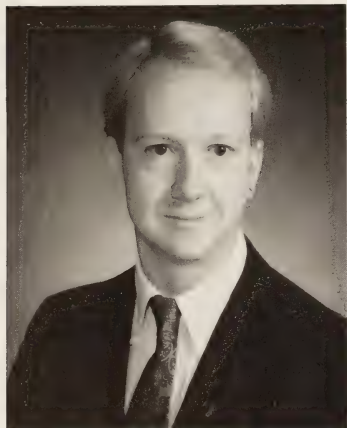
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## DUR From a Student's Perspective

*Randy R. Delker, PEP Student, Mid-Atlantic DUR, Inc.*



Good God, here I go again. Another PEP rotation, another month of working for free, another month of possible boredom. These thoughts went through my mind as I was preparing to begin my rotation at Mid-Atlantic DUR. DUR seemed like a silly notion. What sense did it make to review a patient's profile months after the medication was dispensed? Isn't it too late then? Haven't all the serious adverse drug reactions already occurred and now resolved? I was quick to learn that I was very wrong.

DUR. Drug Utilization Review involves examining a patient's profile for problems that may alter the therapeutic outcome for the patient. Information derived from provider claims are put together by a computer to generate the patient profiles. DUR does not second guess the prescriber or the pharmacist, but looks from an outcome perspective and makes therapeutic suggestions to both health care providers. Using the patient profiles, the DUR reviewer can check for overutilization and underutilization of medications and services, multiple prescribers and pharmacies, interactions, contraindicated conditions and possible abuse.

DUR does not take the place of patient counseling at the pharmacy level. It enhances the effective communication between physician, pharmacist and patient. DUR can provide information that may not be available to the individual practitioners. If a patient is using several doctors and pharmacies, the individual provider may not know this and may treat the same condition again with similar or identical therapy. This adds unneeded expense to the health care system. This month, I personally have observed DUR in action. For example, take the case of Ms. X. She has been diagnosed with a seizure disorder and her physician has prescribed Dilantin. A review of her DUR profile shows that she has had several episodes of seizures. Her physician has increased her dosage of Dilantin in hoping to provide adequate protection. From her patient profile, it was clear that Ms. X used several pharmacies and was not compliant with her Dilantin medication. Poor compliance resulted in inadequate blood levels and allowed the development of seizures. A letter addressing this problem was sent to Ms. X's physician and the pharmacies that she frequented, making her health care providers aware of this case of underutilization. Six months later, a new profile was generated on Ms. X and the problem had been resolved. The patient was compliant and no further episodes of seizure noted.

However, DUR is not without its disadvantages. It is impossible to monitor for acute adverse reactions and this important task is still left to the community practitioner. Furthermore, many view DUR as intrusive to their personal practice.

Both physicians and pharmacists have expressed their displeasure with someone else "checking up on them." However, the overwhelming majority of providers of medical services express gratitude to the program for making them aware of problematic situations that they were unaware existed.

With the profession of pharmacy moving from dispensing product to dispensing service, drug utilization review is an added and valuable tool that pharmacists may use to provide complete patient care. ■

# Spotting Questionable Prescriptions

*Glen Lichtman, P.D., Clinical Reviewer, Mid-Atlantic DUR, Inc.*

As a member of the Region I Drug Utilization Review Committee (Baltimore City), I see many profiles for patients receiving prescriptions from more than one pharmacy and doctor. These prescriptions are usually for controlled dangerous substances and are filled with abnormal frequency. The following scenarios are representative of situations you may find yourself in when presented with prescriptions from doctor and pharmacy "shoppers."

## **The Rush Act**

This patient comes into your pharmacy like a hurricane. The door is thrown open and all you see is a blur rushing towards you with a paper in hand. The patient hurries up to the drug counter and announces, "Doc, I need this filled right away." The patient will not leave the counter and follows your every move.

**Rationale:** The name of this game is intimidation. The patient does not want you to have time to phone the doctor, or take the time to study either him or herself or the prescription.

**Solution:** Tell the patient you have several prescriptions ahead of his or hers, and it will be at least 20 minutes. The patient will rarely wait this long, and will leave, returning at a latter time. This gives you time to call the doctor, check patient profiles, and assess whether or not this is a legitimate prescription warranting filling.

## **Your Best Friend**

A loud, booming voice greets you from half way across the store, "Hey, Doc, how ya doin'. Can ya fill this for me?" You look up to see a person you have never seen before waving a prescription at you. Your suspicion deepens as you look at the controlled substance prescription presented to you. A search of your computerized patient profiles reveals that the patient has never had a prescription filled in your pharmacy.

**Rationale:** The patient hopes you will be too embarrassed to admit you do not recognize him or her and will fill the prescription without questioning it.

**Solution:** Tell the patient they are not in your computer records and will need some specific information to create a file before filling the prescription. Buy time to analyze the prescription for authenticity before filling.

## **Price Check, Please**

A patient calls asking, "How much for 100 Tylox, Doc?" You quote the price and minutes later a prescription for Tylox is brought in for filling. Sometimes the caller may ask if the drug is in stock.

**Rationale:** This tactic eliminates an easy out for you. You no longer can claim to be out of stock.

**Solution:** When called, feign busyness, and request a name and phone number for a return call. Patients using this scam will rarely leave a responding phone number. But beware -- a local gang in Baltimore city has given a return number, which is a pay phone or cellular phone.

## ***Legitimate Drugs for Illegitimate Uses***

Believe it or not, drug abusers have found a number of non-FDA approved uses for legitimate prescription drugs. Did you know the illegal uses for the following?

*Clonidine (Catapres)* -- Heroin and morphine addicts use it when coming down too fast from a high and to tide them over between hits. Usual strength per dose used is 0.3 mg.

*Carisoprodol (Soma)* -- Used for alleviating symptoms of cocaine withdrawal. Also, known as the poor man's "Quaalude".

*Promethazine (Phenergan)* -- Obtained either as a syrup or tablets. The syrup is preferred because it is easier to fake a cough for the prescribing physician. It is used to enhance highs from opiates.

*Albuterol (Proventil or Ventolin)* - The inhalers are used by cocaine addicts (smokers or inhalers) prior to inhaling cocaine. This clears the bronchioles and enhances the absorption and high from the cocaine.

### The Mystery Caller

Hi, I'm Dr. So-and-so. I am calling in a prescription for (controlled substance of choice)." The "Doctor" calls in quickly and hangs up before you have a chance to ask any questions. Shortly thereafter, another phone call is received from a patient, inquiring whether a prescription has been phoned in for them. This is also a favorite trick for evening or weekend hours, when doctors' offices are closed.

**Rationale:** This patient hopes you will be in awe of the doctor's authority, and not question a phoned-in prescription.

**Solution:** When a doctor phones in a scheduled prescription and I am unfamiliar with him/her, I tell the caller I must access the patient profile before taking the prescription. If the patient is not in our system or has a history of controlled drug use, I inform the physician of such, and ask for a written prescription before filling.

### The Traveling Patient

You are presented a suspicious prescription. The patient's address is not local and the prescribing physician is from across town. An alarm bell should be going off in your head. Unless the patient happens to work nearby, what has brought him or her to you?

**Rationale:** The patient knows you are familiar with the handwriting and prescribing habits of doctors in your area. He or she hopes you will not notice irregularities on the prescription of a doctor you do not know. Why does he or she come to you from out of the area? Perhaps the pharmacies near his home know him or her, and will not fill controlled substance scheduled prescriptions.

**Solution:** Explain to the patient that, from a professional standpoint, you do not fill prescriptions from physicians that you are unfamiliar with. If this is an emergency, offer to call the pharmacy that the patient normally deals with to verify their medication profile so as to avoid any interactions. ■



## Drug Product Problem Reporting Program



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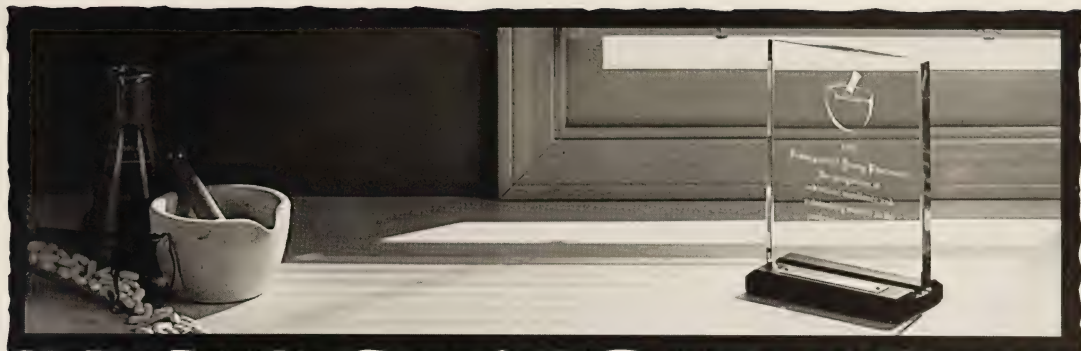
**Reports may be submitted in writing** using a USP report form or by calling USP toll free. The manufacturer or the FDA may contact you directly to discuss your concerns and USP will forward to you any information we may receive.

**Your reports will be computerized and correlated** with reports from other health professionals. This will allow for trend analysis of medical products on the market.

**Your input is needed** to help provide a complete picture of current trends for a more accurate evaluation of these products. Reports of problems experienced in your practice will help to provide practical input into the improvement of compendial standards in the USP/NF or drug information monographs in the USP DI.

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# Nurse Practitioner Prescriptions

## *The Board of Pharmacy Answers Pharmacists' Questions*

Steven Cohen, P.D., President, Maryland State Board of Pharmacy



What can a nurse practitioner prescribe? Can nurse practitioners prescribe controlled dangerous substances? Most importantly, what can a pharmacist dispense when the prescription is written by a nurse practitioner?

Several MPhA members have had conflicts with nurse practitioners who believe their right to prescribe is broader than that defined in law and regulation. At MPhA's request, the Board of Pharmacy provided pharmacists with clarification on this confusing issue. The following information is extracted from a letter sent to MPhA by the Board of Pharmacy on August 20, 1992.

1. Nurse practitioners (NP) may prescribe any drug other than controlled substances if it is within his/her scope of practice. The scope is defined in a written agreement between the nurse practitioner, the collaborating physician, and the Board of Nursing. All nurse practitioners must have such an agreement on file with their Board and any pharmacist with a question can call the Board of Nursing for clarification.
2. All nurse practitioners must clearly indicate on the prescription that they are a nurse practitioner.
3. The same burden of validating the prescription exists for the pharmacist filling a prescription written for by a nurse practitioner as does for any authorized prescriber. The only practical difference is that one has the agreement on file to check, if necessary, for clarification.
4. Nurse practitioners can prescribed controlled substances on their own *only* if they have their own DEA number. Early on, DEA numbers were issued for nurse practitioners. That is no longer being done. Nurse practitioners *cannot* use their collaborating physician's DEA number. In cases where nurse practitioners do not have their own DEA number, they *cannot* prescribe controlled substances.
5. New federal regulations are pending to modify the issue of affiliated professionals, such as physician assistants, nurse practitioners, and certified nurse midwives and others regarding the prescribing of controlled substances. Keep an eye on the Federal Register for more information.

To verify the written agreement between the nurse practitioner, the collaborating physician, and the Board of Nursing, call the Board of Nursing at (410) 764-4747. ■

# Update: No Arbitration for Pharmacists

David B. Brushwood, J.D.



The Court of Appeals of Maryland recently reviewed the scope of a state law that requires arbitration prior to the filing of a medical malpractice claim. Specifically, the court was asked to rule on whether claims for damages against a pharmacist for errors in connection with the dispensing of a prescribed drug would fall within the arbitration requirement.

The plaintiff alleged that a pharmacist at a pharmacy owned by the defendant filled a prescription with chlorpropamide, rather than with Corgard, which had been prescribed. The patient went into a diabetic coma, and suffered a serious and life-threatening injury. She filed a lawsuit alleging that the pharmacist was negligent in failing to fill her prescription correctly. The trial court dismissed the case because the plaintiff had not complied with the arbitration requirements of the health care malpractice statute. The plaintiff appealed.

On appeal, the court determined that it would resolve the case by first examining the plain meaning of the words in the statute, and then by determining the intent of the legislature. The essence of the law was to require arbitration prior to filing a lawsuit against a "health care provider" based on "medical injury."

According to the statute, "health care provider" was defined as "a hospital, a related institution, a physician, an osteopath, an optometrist, a chiropractor, a registered or licensed practical nurse, a dentist, a podiatrist, and a physical therapist." "Medical injury" was defined as "injury arising or resulting from the rendering or failure to render health care."

The plaintiff argued that the legislature intended the list of health care providers to be exhaustive, not merely illustrative. In support of her argument, she pointed to the fact that the legislature had recently added psychologists and social workers to the list, and would not have needed do so unless the list was intended to be exhaustive. She also argued that she did not suffer a "medical injury," because the filling of a prescription and/or the labeling of the medication dispensed does not constitute the rendering of health care, but rather is the sale of a product.

The defendant urged the court to look beyond the language of the statute and to interpret the statute to mean that pharmacists were included. The defendant pointed to the fact that pharmacists are regulated by the state of Maryland under the section of the law applicable to health occupations. The defendant also cited several out-of-state cases in which pharmacists had been described as providers of a health care service rather than as sellers of a product.

The court was persuaded by the plaintiff's arguments. The court ruled that the arbitration requirement does not extend to claims made against pharmacists. The legislature had not listed pharmacists, and the list was determined to be exhaustive. As a result, pharmacists will have to sponsor legislation to have themselves included on the list if they wish to have the protection from litigation that the arbitration requirement affords. ■

Based On: Mancuso v. Giant Foods, 1992 Westlaw 168210 (Md. App. July 23, 1992). Copyright 1992, David B. Brushwood. All rights reserved. Reprinted from *Dickinson's Pharmacy*, 8/92.



# DRUG PRODUCT QUALITY Review

A PUBLICATION OF THE USP DRUG PRODUCT  
PROBLEM REPORTING PROGRAM

No. 23

## SOME GOOD CAN COME FROM REPORTING MEDICATION ERRORS

As pharmacists are aware, the United States Pharmacopeia (USP) sets standards of strength, quality, purity, packaging, and labeling for drug products available in the United States. For the past twenty years, pharmacists and other health care professionals have been able to address problems with product quality through the USP Drug Product Problem Reporting Program (DPPR).

Recently, the USP undertook the coordination of the Medication Errors Reporting (MER) Program for the Institute for Safe Medication Practices, Inc., of Huntingdon Valley, Pennsylvania. The MER Program, founded by the Institute in 1975, is the latest addition to the USP-Practitioners' Reporting Network (USP-PRN). The MER Program provides the opportunity for health care professionals to report medication errors that occur in their practice and thus prevent future errors. The USP will focus primarily on the product and its label, to learn of those instances where a product's design or characteristics may contribute to an error. As a result, USP requirements can be modified, if necessary. The Institute's focus is on any error, actual or potential, for which educational programs for practitioners or practitioner guidelines can be developed to help prevent occurrences or recurrences.

While the DPPR Program is used for problems relating to drug product quality, the MER Program encompasses a wider variety of problems of misinterpretations, miscalculations, and misadministrations that may be encountered in health care practice. Problems reported through the MER Program include difficulty in interpreting handwritten orders or misunderstanding verbal orders, instruction-for-use information that is unclear to the product user, and unfamiliarity with new products that leads to improper use. The program has also received reports of similar or confusing product names, similar packaging or labeling that can encourage errors in dispensing or administration, and unclear wording of labels, all of which can result in an incorrect dosage or route of administration. The following case studies are examples of reports submitted to the MER Program.

### **CASE NUMBER ONE: Does D/W mean "Dextrose in Water" or "Distilled Water"?**

A pharmaceutical manufacturer uses initials on the labels of its large volume parenteral products. One such abbreviation is "D/W," apparently to indicate "Distilled Water." In addition, the firm properly states the product ingredients on the label, namely, Sterile Water for Injection. However, the "D/W" on the label is highlighted, drawing attention to it rather than the full product name. In compounding an intravenous medication, pharmacy staff assumed "D/W" indicated "D5%/W," a common abbreviation for dextrose 5% in water. A pharmacist realized the error before any medication was dispensed.

### **CASE NUMBER TWO: What is the proper abbreviation for subcutaneous—S.C. or S.Q.?**

A nurse interpreted a physician's order as Heparin 5000 units every 2 hours, instead of Heparin 5000 units 2 hours prior to surgery. The operation was canceled until the following day. On the original handwritten order, Heparin 5000 units s q 2 h before surgery, the q was closer to the 2 than to the s, hence the order was misinterpreted.

Since its inception, the MER Program has published more than 600 reports and issued warnings about potentially dangerous labeling and packaging of pharmaceuticals that may encourage errors by their design. With the vast number of medications available, the variety of medication delivery devices on the market, and the ever-changing technology in health care, the chance of errors increases. Some good can come from reporting medication errors. In sharing information with other health care professionals, the recurrence of an error may be avoided. With a heightened awareness about potential problems, safeguards can be instituted to avoid them, thereby promoting better patient care.

To submit reports of problems or potential problems to the MER Program, health care professionals may call 1-800-23-ERROR. A voice-prompted answering device will record the problem, enabling reporters to remain completely anonymous, if so desired. To speak to someone about the program or any of the other services of the USP-Practitioners' Reporting Network, call the USP-PRN at 1-800-638-6725.

# Drug Information Questions

## *Using Cough and Cold Preparations in Pregnancy*

Denise Mawakani, Babette S. Prince, Pharm.D., UMAB Drug Information Center

This article provided under a grant-in-aid from **Glaxo**

### **Drug Information Request**

What cold and cough preparations can be used during pregnancy?

### **Response**

During pregnancy, many common ailments occur that require drug treatment for control of symptoms. Among these are headache, gastrointestinal complaints, infections, colds and allergies. There is still little information about the potential danger of drug utilization during pregnancy. However, the prevalence of drug usage is not decreasing.<sup>1</sup> Numerous studies conducted from 1967 to 1987 concluded that pregnant women took at least 4.7 different drugs throughout their pregnancy.<sup>2</sup>

Of all medications used during pregnancy, 68 percent were over-the-counter and the 32 percent were prescription drugs. Over-the-counter cold preparations contain various combinations of ingredients such as sympathomimetics, antihistamines and analgesics. Cough suppressants (dextromethorphan), expectorants (guaifenesin) and other ingredients like alcohol and local anesthetics may also be included.<sup>3</sup>

Teratogenic potential has not been clearly demonstrated for the general group of antihistamines contained in over-the-counter cold and allergy medications or nasal sprays. However, single ingredients that may be linked with minor birth defects have been identified. Brompheniramine, dextrobrompheniramine and chlorpheniramine should not be used during the third trimester because of the risk of seizures to neonates.<sup>4</sup> These drugs should be used during the first two trimesters only when the potential benefits justify the possible risks to the fetus. These risks involve malformations including eye and ear defects, inguinal hernias and congenital dislocations of the hip.<sup>5</sup> Diphenhydramine usage during the first trimester has been associated with an increased risk of cleft palate alone or in combination with other fetal deformities.<sup>4</sup> Possible associations with individual malformations, including eye and ear defects, inguinal hernia, clubfoot and hypospadias were found, but independent confirmation is needed to determine the actual risk involved.<sup>6</sup> Also, antihistamine exposure within

two weeks of premature delivery has been associated with an increased frequency of retrolental fibroplasia in neonates.<sup>7</sup>

Sympathomimetics present a different profile of teratogenic effects. Administration of phenylephrine in late pregnancy or labor may cause fatal anoxia and bradycardia in the fetus by increasing the contractility of the uterus and decreasing uterine blood flow.<sup>8</sup> Phenylephrine should be used throughout pregnancy only when benefit to the mother outweighs risk to the fetus. Possible risks to the fetus associated with its use include congenital dislocations of the hip, umbilical hernias and other musculoskeletal defects.<sup>9</sup> Phenylpropanolamine should not be used early in pregnancy because of possible containment of hemorrhage and edema in the endometrial lining.<sup>8</sup> There are no reports regarding its safety during the rest of pregnancy. Pseudoephedrine safety has not been established but again, should be used only if the potential benefits outweigh the risks to the fetus.<sup>8</sup>

Several additional ingredients used in cough and cold preparations may or may not be associated with teratogenicity. Alcohol has definitely been associated with teratogenicity and these birth defects have been labeled as the "fetal alcohol syndrome (FAS)." Signs and symptoms of FAS include cleft palate, severe mental retardation, growth retardation and various organ system damage. Daily ingestion of even the small amount of alcohol contained in cough syrups throughout pregnancy can cause these problems in the neonate.<sup>10</sup> However, the exact amount of alcohol that causes these problems is unknown. Expectorants like guaifenesin have not been identified with any teratogenic effect but again, should be used only when needed. It is unknown whether the antitussive dextromethorphan is associated with teratogenic effects.<sup>11</sup> However, codeine exposure during the first trimester has been identified with possible malformations including inguinal hernias, cardiac and circulatory system defects, cleft lip and palate, and musculoskeletal defects.<sup>12</sup> Second trimester exposure has been associated with alimentary tract defects. Also, codeine withdrawal symptoms can be observed in infants of mothers who ingested large

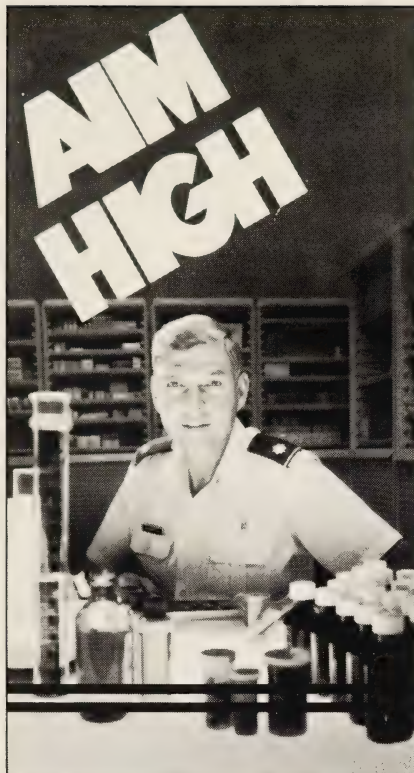
amounts of codeine in late pregnancy.<sup>12</sup> Respiratory depression may also be seen in neonates whose mothers ingested codeine during labor.<sup>12</sup> It is unknown whether Tessalon<sup>R</sup> or benzonatate, a nonnarcotic and antitussive agent, can cause fetal harm, due to the fact that animal reproduction studies have not been performed. It should be given to pregnant woman only if the benefit to the mother outweighs the risk to the fetus.<sup>13</sup>

Analgesics commonly ingested during pregnancy are acetaminophen and aspirin. Acetaminophen has been used at all stages of pregnancy. Although it crosses the placenta, there appears to be no teratogenic effects when acetaminophen is taken in recommended doses.<sup>14</sup> On the other hand, aspirin use should be avoided during the last trimester because the drug affects maternal and infant hemostasis.<sup>15</sup> The effects that may occur include an increased risk of hemorrhage, increased perinatal mortality, intrauterine growth retardation, and teratogenic effects. There have also been reports of premature closure of the ductus arteriosus, prolonged gestation, prolonged labor and intracranial hemorrhage in premature infants when aspirin was used during late pregnancy.<sup>15</sup>

The use of OTC drugs by pregnant women has been documented but few drugs are known to be safe for the developing embryo. Pregnant women should first try nonpharmacologic methods like bed rest, fluid intake to prevent dehydration, local heat and humidification for their cold or allergy symptoms. If these methods fail, normal saline drops may be tried for nasal congestion before using any drug like sympathomimetic agents. Normal saline drops or sprays (Afrin Saline Mist<sup>R</sup>, Ocean<sup>R</sup>) can be used in each nostril, two to six sprays or drops per day as needed. Single ingredient preparations like pseudoephedrine or guaifenesin may also be attempted before using combination products but only if the benefit to the mother outweighs possible risk to the fetus. Pharmacists who recommend nonprescription drugs need to know the effects of OTC medications on the unborn and the newborn in order to recommend appropriate therapies. ■

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# Cost Effective Antibiotic Therapy

Dennis E. Ferguson, P.D., Clinical Reviewer, Mid-Atlantic DUR, Inc.

With the introduction of several new antibiotics in the past several years and the aggressive detailing by the pharmaceutical industry, the challenges to cost-effective and rational drug therapy become evident.

Antibiotic resistance has been reported to have increased with the widespread use of ciprofloxacin. In one report, *Pseudomonas aeruginosa* which was 100 percent susceptible in 1988 was found to be only 55 percent susceptible in 1990.<sup>1</sup> In the same report, *Staphylococcus aureus* which was 94 percent susceptible in 1988 was only 80 percent susceptible in 1990 and *Enterococcus sp.* was 92 percent in 1988 versus 65 percent in 1990.

*The Medical Letter* recently reported cost comparisons of various antimicrobials.<sup>2</sup> The cost to the pharmacist for ciprofloxacin, norfloxacin, ofloxacin and amoxicillin-clavulanate was between \$4.32 and \$6.36 for one day's therapy. In contrast, the cost to the pharmacist for a day's supply of generic double strength trimethoprim-sulfamethoxazole was only \$0.44. Their conclusion was, "overuse leading to development of bacterial resistance presents a serious threat to the long-term usefulness of these drugs."

A recent survey of antibiotic prescribing practices in a 90 bed nursing home was performed by this author. Of twenty-six orders selected for review during a three month period, three orders were for an antibiotic to which the organism was resistant (11.5 percent), nine orders did not include a culture (34.6 percent), and eighteen orders were not cost-effective (69.2 percent) -- a less expensive antibiotic was also effective and would have resulted in a cost savings of \$150 to \$200 per month.

One final concern other than the cost and resistance potential is the association of broad spectrum antibiotic use with the development of antibiotic-induced pseudomembranous colitis. This iatrogenic problem may be avoided by the appropriate use of narrower spectrum antibiotic therapy. In today's economic and regulatory climate, more attention to rational cost-effective antibiotic therapy is encouraged. ■

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## On the Corner

Frank McGinity, P.D.

According to Maryland law, prescribers must write prescriptions legibly and have an identifiable signature. I thought you'd enjoy deciphering this prescription I recently received. The answer will appear in next month's *The Maryland Pharmacist*.

In the meantime, send or FAX prescriptions even Sherlock Holmes couldn't figure out to "On the Corner," MPhA, 650 West Lombard Street, Baltimore, MD 21201, FAX (410) 727-2253.

Prinidin 0.325  
# 200  
os. Dr. [Signature]

# Dickinson's Pharmacy

Jim Dickinson

"Totally invisible" pharmacy. "I mean, what do we pay our dues to APHA and NARD, if pharmacy can't get into the public discussion of health care? It's like we're totally invisible as a profession."

That complaint by Larry Wolfe, owner of Hathaway Pharmacy in the Philadelphia suburbs, struck a chord. He said he's just watched one talk show too many without a pharmacist among panelists from medicine, insurance, government, consumer activists, nursing etc.

Could it be, I asked Larry, that the producers of all these programs don't see pharmacy as being part of the problem?

"If we beat on their doors hard enough and often enough, they wouldn't dare turn us away," he retorted. Then he turned me away--something more important, a customer, had come into view -- and he got off the phone abruptly.

Larry's complaint is an old and frequently expressed one, only now it has a new urgency.

The future of health care in America is being debated, and minds are getting locked into prideful, defensive positions that may ultimately be unnecessarily rigid.

When it's all over -- not this year, but maybe next -- will pharmacy again be where it has so often been left in the past: holding a "done deal" that it doesn't like?

If pharmacists pay their dues to have their national associations fix everything without their own direct participation. What are those national associations in fact doing for their money?

I took this question to the American Pharmaceutical

Association, where director of government relations Bill Hermelin took the call.

He agreed that pharmacy as a whole has not yet "got its act together" so far as the public debate on the broad structural issues of national health policy is concerned.

---

*The future of health care is  
being debated.  
Why isn't pharmacy's voice  
being heard?*

---

But it's dead wrong, he said, to think that pharmacy is "invisible" in government -- the profession had major, and successful input on the Medicare Catastrophic Act a few years ago, and more recently on OBRA '90 (Omnibus Budget Reconciliation Act), which is currently being felt through Medicaid drug utilization review and counseling provisions, among other impacts.

But the critics are right, Hermelin conceded, in the pharmacy successes tends to occur only in focussed pharmacy-dominated arenas, not the broad health policy "structural" arenas.

At the recent Ohio State Pharmaceutical Conference, he and panelists from the American Society of Hospital Pharmacists and the American Society of Consultant Pharmacists agreed that a more aggressive posture is needed by the profession on broad health policy.

Hermelin believes that the profession at the national level has to decide whether its voice will be injected into broad health policy discussion by one representative

organization (such as the Joint Commission of Pharmacy Practitioners), or by each of the existing national associations.

This is currently being considered by all the organizations on an urgent basis, so that pharmacy is not left behind.

Hermelin has some other pertinent observations to make on the issue. For example, much as the Larry Wolves of pharmacy may lament pharmacy's absence from the debate about health care, more health care providers are (like pharmacy) left out than are included.

Podiatrists, ophthalmologists, dentists, long-term care facilities, paramedics, psychiatrists, emergency clinics, etc., etc., all are frustrated in adding their contributions.

And if -- as we all believe -- pharmacy's contributions ought to be recognized as being able to make a major impact on the rate of cost escalation in other sectors, then part of the blame for that not being more widely accepted lies with manufacturers.

Even though belated efforts are now being made by industry to spread the word about the positive benefits of pharmaceutical companies are far from unanimous about how much to say and who to say it to.

One of the reasons for this muffled tower of pharmaceutical babel is the undeniable fact that hardly anybody can agree on what to say. Is the drug bill itself too high? Can pharmacists cut its cost through DUR and counseling? Which companies would lose if they did? Why should they pay for tat message?

*Continued on page 31....*

# Continuing Education

## Continuing Education Quiz

October 1992 -- DUR

This month's questions are taken from the articles in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by March 31, 1993. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name \_\_\_\_\_

Social Security Number \_\_\_\_\_

Address \_\_\_\_\_

City/State/ZIP Code \_\_\_\_\_

Is this program used to meet your mandatory CE requirements?

☐ Yes ☐ No

Was this issue/article useful to you in your practice?

☐ Yes ☐ No

1. Nurse practitioner may write prescription orders for controlled substances if:
  - a. they have a contract with the Nursing Board
  - b. they have their own DEA number
  - c. they use a physician's DEA number
  - d. a and c only
  - e. a and either b or c
2. Prospective and retrospective drug utilization review for Medicaid recipients was mandated by:
  - a. OBRA 1987
  - b. OBRA 1990
  - c. Maryland Senate Bill 151
  - d. Board of Pharmacy regulations
3. When reviewing a "high risk" profile, DUR reviewers look for which of the following?
  - a. overutilization of medications
  - b. potential drug/disease contraindications
  - c. underutilization of medications
  - d. all of the above
4. Federal regulations, implemented under OBRA '87, substantially changed the prescriptions for nursing home residents are dispensed. Which of the following drug classes was impacted the most?
  - a. NSAIDs, antihypertensives, antidepressants
  - b. antihistamines, NSAIDs, antihypertensives
  - c. antipsychotics, anxiolytics, antidepressants
  - d. antihypertensives, anxiolytics, psoralens
5. When presented with a questionable CDS prescription, the pharmacist should always:
  - a. contact the prescriber before dispensing
  - b. contact the prescriber after dispensing
  - c. contact the Board of Pharmacy
6. In *Mancuso v. Giant Foods*, the court ruled that Maryland law requires arbitration before a negligence or malpractice suit can be brought against a pharmacist.
  - a. true
  - b. false
7. Which of the following cough and cold product ingredients have been linked to teratogenicity and birth defects.
  - a. alcohol
  - b. codeine
  - c. diphenhydramine
  - d. a and b only
  - e. a, b and c can cause birth defects
8. According to one study, resistance to ciprofloxacin has \_\_\_\_\_ with inappropriate prescribing since 1988.
  - a. decreased
  - b. increased
  - c. leveled off
9. The patient profiles used in retrospective DUR are generated from which of the following:
  - a. physician claims only
  - b. pharmacy claims only
  - c. hospital and clinic claims only
  - d. physician, hospital and pharmacy claims
10. Computerized therapeutic criteria are used to:
  - a. generate educational intervention letters
  - b. assemble patient profiles from claims data
  - c. screen and identify "high risk" patient profiles
  - d. eliminate manual review by clinical reviewers

## Dickinson's Pharmacy

*Continued from page 29.*

Is the drug bill in fact too low, vis-a-vis the bill for needless surgery and wasteful lab tests? What is the cost of prescriptions never filled, and who pays?

Such questions -- like Larry Wolfe's complaint about the "invisible pharmacist" -- have been around a long time. What's different now is that everybody seems to be waking up to the need for urgent solutions, so that pharmacy can take its rightful place in the health care reform "structural" debate.

This is where you come in. Don't close your involvement when you close the flap on the dues envelope you send to your national association.

Put your own dollars to work as well, by spreading the pharmacy cost-effectiveness message. You can do this with in-store posters, letters to the editor, public service announcements on local radio or television, speeches to Rotary and other civic groups, and even with the remark, "Think what our health might cost if you didn't take your medicines! whenever you deliver a filled prescription.

All such efforts to build pharmacy help at the same time to build public opinion and hasten the day when pharmacy takes its rightful place on the platform of the national health debate.

When that finally happens, a lot of people will be pleasantly surprised to discover what pharmacy can do.

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This feature is presented on a grant from Dickinson's Pharmacy -- *The Independent Voice*, a professionally stimulating monthly newsletter available for \$45 a year plus your retail pharmacy's label from Ferdic, Inc., PO Box 848, Morgantown, WV 26507-0848.

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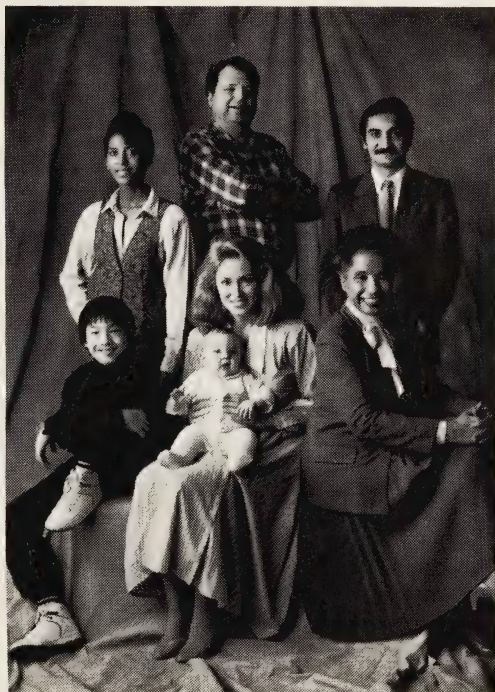
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# The Maryland Pharmacist

VOL. 68

November, 1992

No. 11



*Living with*  
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# The Maryland Pharmacist

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650 West Lombard Street, Baltimore, Maryland 21201-1572  
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# President's Commentary

## Thoughts About Two Issues

Nicholas C. Lykos, P.D., President



Now that the colors of the fall leaves signal the month of November, we are reminded that this is **National Diabetes Month**. This chronic disease, which strikes all ages, can be controlled with proper counseling, exercise, and medication. It would behoove our nation's health community to somehow alert the public and develop a system for early detection of this disease. With pharmacists so nationally available to the public, we could play a crucial role in detecting diabetes mellitus. Educating the early diagnosed patient will conserve many lives, health care dollars and employee hours.

The pharmacist plays a critical role in treating diabetic patients. These patients have a great economic impact on the pharmacy and the pharmacist has an equally great responsibility in treating and educating their patient. In this dedicated issue prepared by Beverly Yachmetz, Pharm.D., C.D.E., you will identify your position in the treatment.

This month, every month, and everyday pharmacists should strive to make a positive health care accomplishment.

Our state pharmacy laws and regulations clearly define manufacturers and distributors as well as manufacturing and distributing. Compounding -- specifically pharmacy compounding -- is not defined. Unfortunately, the art of compounding has eroded over the years with the proliferation of prepackaged medicines and stringent Federal manufacturing guidelines. Some pharmacists have seen compounding as a way to establish a specialized market niche for their practice. Unfortunately, I think that some of those pharmacists have taken this as a license to circumvent the intent of the law. Compounding is not preparing a generic ophthalmic solution from a pharmacy in one state for other pharmacies' patients in other states. Compounding is not preparing a topical DMSO as a Georgia pharmacist did. Compounding is not the mass production of indomethacin ophthalmic solution in a Pittsburgh pharmacy.

The blatant abuse of the art and right of compounding by these pharmacists caught the attention of the Food and Drug Administration. Several pharmacists nationally have experienced the overzealous wrath of FDA officials who claim that pharmacists cannot compound without first filing a New Drug Application (NDA). Or worse, that the art of compounding falls under the direct jurisdiction of the FDA. FDA Commissioner David Kessler has told national pharmacy organizations that FDA has no intention of eliminating the pharmacist right to compound medications; however, he has made it clear that FDA will investigate and prosecute any incidences of blatant abuse of the compounding art.

And the sad thing is, none of this would have happened if a few pharmacists had'n't been so greedy. ■

# Non-Insulin Dependent Diabetes Mellitus

## *What's New in Treatment*

*Beverly Yachmetz, Pharm.D., C.D.E., Clinical Coordinator  
Diabetes Care Management Program, Liberty Medical Center*

For the past several decades, there have been few options for pharmacological treatment of non-insulin dependent diabetes mellitus (NIDDM). Advancements in monitoring capabilities (home blood glucose monitors, glycated hemoglobin) coupled with the necessity to prevent or delay complications have placed tremendous emphasis on tight glycemic control. Research efforts have intensified resulting in several promising agents. The following is a profile on the agent predicted to be released in early 1993.

Metformin, a biguanide, is currently in the final trials in the United States. The biguanide class has previously been used in the U.S. market. The most notable of this group is phenformin which was removed from the U.S. during the 1970's due to an association with lactic acidosis. Metformin is now the biguanide of choice in the world market, excluding the U.S. market. This drug accounts for one quarter of all prescriptions for oral glucose lowering agents in Great Britain.

Biguanides, specifically metformin, are best described as antihyperglycemic agents, rather than hypoglycemic agents. Metformin does not cause hypoglycemia, even when ingested as an intentional overdose. When metformin is used as monotherapy, studies indicate there is a greater than 20 percent reduction in basal glucose concentrations<sup>1</sup>. The antihyperglycemic effect shows no association with the extent of hyperglycemia before treatment, age, duration of diabetes, body weight, or basal insulin concentrations<sup>2</sup>.

There are multiple physiological problems which can result in increased blood glucose. The mechanism of action for metformin has been investigated in context of these physiological problems. Studies indicate the therapeutic effect is not due to increased insulin levels. In addition, metformin has little or no effect on secretion of the counter regulatory hormones (glucagon, somatostatin, growth hormone, or cortisol). Hepatic glucose output has not been consistently decreased with metformin treatment although overall glucose levels have declined. The most significant mechanism of action detected is an increase in insulin-mediated glucose utilization. The most convincing evidence for this effect comes from reports that insulin requirements are reduced

by metformin treatment in overweight, insulin-treated NIDDM patients. Metformin may improve insulin sensitivity by increasing insulin receptor binding in individuals with a reduced number of insulin receptors. However, due to the large number of spare receptors, the more significant activity appears to be a post-binding effect which is currently under investigation. An additional mechanism includes a reduced rate of intestinal glucose absorption<sup>3</sup>.

---

*The newest agent available for diabetes mellitus, metformin, works as an antihyperglycemic*

---

In addition to lowering blood glucose levels, studies have shown additional drug effects which are beneficial to the individual with NIDDM. Unlike insulin and the sulfonylurea drugs, metformin does not cause weight gain. Further, metformin has actually been shown to promote weight loss, with an average of 1.2 kg in obese and 1.5 kg in non-obese individuals with NIDDM after one year of therapy. Abnormal lipid profiles are common in individuals with NIDDM, often targeted as contributing to the increased risk on heart disease in the NIDDM patient. This agent has been shown to lower total cholesterol levels and more specifically lower the low-density lipoprotein (LDL) and very low-density lipoprotein (VLDL). Also noted was a small increase in high density lipoprotein (HDL), the so-called "good" cholesterol. Animal studies have demonstrated an antiatherogenic action. Other clinical studies have indicated increase fibrinolytic activity and decreased sensitivity to platelet aggregating agents<sup>4</sup>.

In clinical use, metformin has been studied as monotherapy, and in combination with sulfonylureas and insulin. When used alone, metformin has a primary failure rate of less than ten percent. This rate is similar or slightly better than the sulfonylureas. However, due to a lack of standardization as to the definition of treatment failure, this percent may vary. Estimates of efficacy indicate that less than five percent on individuals cannot

tolerate metformin due to side effects and that greater than 90 percent show improvement in glycemic control. As stated earlier, when used alone, metformin decreased blood glucose levels greater than 20 percent.

Studies of combination therapy with a sulfonylurea have suffered from small sample size and inadequate study time. However due to the different cellular mechanisms, the combination, in theory would enhance glucose control, possibly without increased risk of hypoglycemia due to metformin's lack of drug-induced hypoglycemia. One study of 184 sulfonylurea failed patients investigated combinations of metformin and chlorpropamide noted acceptable improvement in one-half of patients aged 40 to 59, and two-thirds of patients aged 60-74<sup>1</sup>.

There is little available information regarding the combination of insulin and metformin in the literature. However, one study indicated when metformin was added to an existing insulin regimen, the daily insulin requirement was decreased by 16 percent<sup>5</sup>. Due to the current therapeutic emphasis to minimize the dose of insulin, further study of this effect of metformin is warranted.

Metformin is currently available outside the U.S. in 500 mg and 850 mg tablets. The medication should be taken with meals and the dose increased slowly until the desired glycemic control is obtained or a maximum of three grams per day. Initial treatment is 850mg at breakfast or 500mg twice daily, with breakfast and another main meal. The typical dose required is between 1200-1700mg administered in divided doses. The maximum recommended daily dose is three grams.

The side effects of treatment affect up to 20 percent of patients. The effects are mainly gastrointestinal, including diarrhea, abdominal discomfort, metallic taste, nausea, and anorexia. These effects are generally transient and dose related. To prevent these side effects, the medication should be administered with meals and increased gradually. As with phenformin, the risk of lactic acidosis exists with metformin, however the risk is much less. Almost all reported cases occurred in patients with contraindications or in situations of intentional overdose. Contraindications are renal impairment (serum creatinine greater than 120 micromoles/dl) and hepatic disease. In

addition, patients with a history of lactic acidosis, cardiac insufficiency, or any other condition where the patient has difficulty getting oxygen to the tissues (such as severe lung disease) should not take metformin. These individuals have increased risk of anaerobic metabolism which increases serum lactic acid concentrations. Finally, individuals with a history of alcohol abuse should also be excluded. Metformin must be discontinued in individuals who develop renal or hepatic impairment during treatment.

Metformin is an agent which shows promise in the treatment of NIDDM alone and in combination with other glucose lowering agents. In addition to the glucose lowering effects, the weight loss, lipid metabolism and vascular effects may be beneficial to the patient. However, patients must be carefully selected and contraindications followed to prevent severe, life-threatening toxicity. ■

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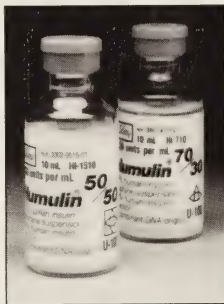
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# About Medicaid's Diabetes Care Program

## *A "Win-Win" Situation*

*Earl W. Schurman, Chief, Division of Diabetes Control, Maryland DHMH*

On June 1, 1991 the Maryland Medical Assistance Program initiated an innovative managed care program for Medicaid-eligible people with diabetes. The goals of the Diabetes Care Program are:

- To reduce medical care costs which result from unnecessary emergency room visits and hospitalizations associated with diabetes

- To provide continuity of care by allowing recipients to select one primary medical provider who manages their care

- Facilitate comprehensive diabetes management, rather than episodic care

- Improve the self-management skills of people with diabetes, and

- To improve health outcomes of people with diabetes

Participation in the Diabetes Care Program is voluntary. To be eligible to enroll in the program, an individual must be currently eligible for Medicaid benefits, have been hospitalized at least one for a diabetes-related condition, and must complete and submit an enrollment form. Individuals who are covered by Medicare, or who reside in a nursing home or other medical institution are not eligible to enroll in the program.

Diabetes Care Program participants are required to select a primary medical provider (PMP). If they have no personal preference for a particular PMP, Medicaid will assign them to an enrolled them to an enrolled PMP who practices close to the participant's home. Participants receive the majority of their medical care from their PMP. Specialty

### *Diabetes in Maryland*

- Approximately 141,000 Marylanders have diagnosed diabetes.
- Approximately 117,500 additional have diabetes but remain undiagnosed.
- Therefore, about 258,500 Marylanders have diabetes.
- Of these, between 13,000 and 26,000 have Type I diabetes.
- The overwhelming majority (232,000 - 245,000) have Type II diabetes.
- Approximately 10,000 Marylanders are diagnosed with diabetes each year.
- Considering these figures, plus the fact that diabetes impacts upon the families and other support persons of those with diabetes plus those who provide patient education and medical care for them, diabetes impacts either directly or indirectly on a large percentage of the citizens of Maryland.
- The combined direct and indirect costs associated with diabetes exceed \$540 million in Maryland each year.
- Diabetes is listed as the underlying cause of approximately 700 deaths in Maryland each year, and as a contributing cause in an additional 2500 deaths annually.
- Diabetes is the cause of an estimated 264 new cases of blindness in Maryland each year. The CDC estimates that 60% of these cases (158 each year) are potentially preventable.

medical care is also covered when the participant's PMP makes a referral.

In an effort to improve patient self-management skills and to prevent or delay the onset of medical

complications of diabetes, the Diabetes Care Program provides coverage for four preventive services which were not previously available to Medicaid recipients with diabetes.

These newly covered services are:

- Individualized nutrition counseling, consisting of an initial 40 minute session and up to four additional 20 minute sessions per year
- Attendance of a structured outpatient diabetes education program (an 8-10 hour course)
- Reimbursement for a self blood glucose monitor and related supplies (previously covered only for those with insulin dependent diabetes), and
- Therapeutic footwear (when prescribed by the PMP)

PMP's provide clinical care within the scope of their own practice, but also are responsible for seeing that all of the medical, educational, and social support needs of their diabetic patients are addressed through a network of diabetes management resources. In return for these services each PMP receives a management fee of \$20 per patient per month, in addition to their reimbursement for office visits. The PMP receives the management fee for each month the participant is under his/her care, regardless of whether the patient was seen that month.

Those eligible to enroll as primary medical providers include primary care physicians in private or group practice, nurse practitioners, and free-standing clinics. They must have or apply for a Medical Assistance provider number, be able to provide 24-hour voice access, and attend a professional education program on clinical diabetes care and comprehensive patient management. This course is offered a coordinated by the Maryland Diabetes Control Program (DHMH's Division of

Diabetes Control), in cooperation with the Maryland Affiliate of the American Diabetes Association. There is no charge for this course, and PMPs earn continuing medical education credits for attending. To make attendance convenient, the course is offered at locations throughout the state. To date, the Diabetes Control Program has conducted the course sixteen times, reaching a combined audience of more than 300 PMPs.

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*All Medicaid clients with diabetes are covered for any diabetes-related medications and all clients with insulin dependent diabetes are covered for self blood glucose monitoring equipment and supplies*

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More than 2,200 Medicaid-eligible Marylanders with diabetes, and over 400 primary medical providers have already enrolled in the Diabetes Care Program. Recently, Medical Assistance Program staff conducted a preliminary survey to determine the level of participant satisfaction with the program. Although the results showed that those enrolled were very satisfied with the care they are receiving through the program, 26% stated that they have experienced some degree of difficulty in getting either their medications or related supplies. There appears to be some misunderstanding on the part of both Medicaid-eligible people with diabetes and some pharmacists regarding

Medicaid reimbursement for medicines and supplies.

Even prior to the initiation of the Diabetes Care Program, Medicaid provided reimbursement for all medications (including insulin and syringes) and for self blood glucose monitors and related supplies, when prescribed by a physician, for those persons with insulin-dependent diabetes. Those clients with non-insulin dependent diabetes were covered for all of their medications, but not for self blood glucose monitoring equipment and supplies. The coverage described above is still in effect for all persons with the traditional red and white Medicaid card, as well as for those enrolled in Medicaid's new MAC Program. MAC Program enrollees carry a black and gold Medicaid card.

Participants in the Diabetes Care Program have a blue and white Medicaid card with a sticker noting "Diabetes Care". All program participants are covered for their medications. In addition, even those with non-insulin dependent diabetes are covered for self blood glucose monitors and related supplies, when the monitor has been prescribed by the participant's PMP. Coverage for these items for those with non-insulin dependent diabetes is unique to the Diabetes Care Program.

In summary, all Medicaid clients with diabetes are covered for any diabetes-related medications, and all clients with insulin-dependent diabetes are covered for self blood glucose monitoring equipment and supplies, regardless of whether they have the traditional Medicaid card, the MAC Program card, or the

Diabetes Care Program card. Only those non-insulin dependent clients enrolled in the Diabetes Care Program are also covered for self blood glucose monitoring equipment and supplies. Questions about Medicaid coverage for medications and supplies should be directed to Ms. Nanette Rosendale, Chief of the Diabetes Care Program. She can be reached by telephone in Baltimore at (410) 225-5154.

Pharmacists can play an important role in the overall management of their clients with diabetes by noting concerns that these people have about their treatment plans and sharing these concerns with these clients' physicians as well as providing the prescribed medicines and supplies. In addition, pharmacists can help to make their customers who have diabetes and are Medicaid-eligible aware of the Diabetes Care Program and encourage them to enroll.

As the title of this article suggests, the Diabetes Care Program truly does represent a "win-win" situation. The Medical Assistance Program wins because Medicaid clients with diabetes receive cost-effective managed care, which promotes continuity of care. Medical care providers benefit by having more resources available to choose from to manage their diabetic patients comprehensively, and through a \$20 monthly managed care fee for each recipient assigned to them. Finally, and most importantly, people with diabetes who are covered by Medicaid have access to state-of-the-art diabetes care, and the education which enables them to become the key team member in the management of their disease. ■

### ***Resource List of Recognized Outpatient Education Programs***

Your Medical Assistance Diabetes Care Program patients are eligible to attend State-recognized outpatient diabetes education programs. These courses are designed to provide comprehensive education about diabetes mellitus for your patients. They contain information which will aid you in teaching your patients good self-care methods and skills, and will provide them with a better understanding of their disease. In order for your patients to attend a recognized education program you must make a referral.

Currently recognized programs include:

#### **Baltimore City**

The Bon Secours Hospital  
2000 West Baltimore Street  
Baltimore, MD 21223  
Contact: Cheryl Maghfirat,  
Program Director, Diabetes  
Education and Management  
Program  
(410) 947-2203

#### **Baltimore County**

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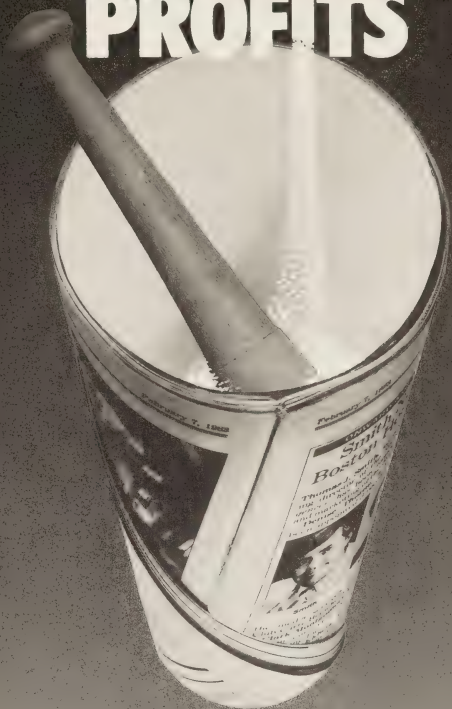
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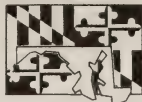
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# Switching Insulins

## Clinical and Legal Implications

Lenore T. Coleman, Pharm. D., and Richard R. Abood, J.D.

Insulin was first isolated and commercially produced in the 1920's.<sup>1</sup> During the last seventy years, commercially available insulin have undergone many developmental changes. These include the crystallization of the insulin molecule, the development of modified insulin, the introduction of protein purification procedures, and the production of human insulin through enzymatic conversion and recombinant DNA technology. All the changes have strived to produce a commercially available pure insulin with the same structure as endogenous human insulin.

Currently insulin is derived from two sources: animal species insulin (pure pork -- porcine, pure beef -- bovine, and beef-pork mixture -- 70 bovine and 30 porcine) and human insulin. The two types of human insulin include: *recombinant-DNA technology (rDNA)* -- biosynthesis of human insulin using either clones of *Escherichia coli* (bacteria), introduced by Lilly in 1983, or *Saccharomyces cerevisiae* (yeast); and *semi-synthetic* -- enzymatic conversion of pork insulin to human insulin by transpeptidation, in which there is replacement of B-30 alanine in pork insulin with threonine. Semisynthetic insulin was manufactured by Novo Nordisk but has been phased out with the introduction of their rDNA yeast product.

There are many factors which affect the time-activity characteristics of the insulin preparations. Some of these factors are outlined on Table 1. Differences can occur between formulations of insulin from one manufacturer to another. These

differences include the source of insulin, purity of composition of the individual formulation. There may be increases or decreases in the incidence of local or systemic allergy, serum insulin concentration, serum antibody concentration and insulin requirement.<sup>2</sup> The study by Galloway et al showed that it is impossible to predict which patients will experience a dose change and in which direction the change will occur.<sup>3</sup>

The clinical implication of switching insulin is based on the kinetics, immunologic and side effect profiles of the different insulin.

### Immunogenicity

Human insulin is substantially less antigenic (i.e., lowering of anti-insulin antibody titer) than bovine-porcine insulin but only slightly less antigenic than purified porcine preparations. Human insulin has a reduced immunogenicity insulin has a reduced immunogenicity (i.e., fewer patients have the induction of insulin antibodies). The importance of circulating antibodies on diabetic control is controversial. In general, the lower the titer of insulin antibodies the better the postprandial glucose control. The long-term metabolic control does not seem to be influenced by the antigenicity of the insulin preparation.<sup>4</sup>

### Kinetics

Human insulins have an earlier onset and peak and shorter duration of action than animal species insulins.<sup>5</sup> This is probably due to human insulins being more rapidly

absorbed after subcutaneous administration. The more rapid absorption of human insulin provides for better postprandial glucose control.<sup>4</sup>

### Side effect profile

The occurrence of lipodystrophies has decreased with the use of "purified monocomponent insulins." Lipatrophy is still reported with the use of both human and porcine insulins. It appears the atrophy may be due to a local immune response. Zinc and protamine in the modified

### Factors Affecting the Time-Activity Characteristics of Insulin Preparations

- dose of insulin used
- site of injection
- depth of injection
- exercise of the injection area
- massage of the injection area
- insulin antibody concentration
- insulin receptor dynamics

Table 1

insulins have been implicated in enhancing the immunological reaction and thereby causing the atrophic process.<sup>6</sup> Lipohypertrophy occurs due to the local anabolic effects of insulin promoting fat and protein synthesis. This effect may occur with any insulin preparation.

Insulin allergy appears to be caused by insulin antibodies. Virtually all

insulin-treated diabetics develop antibodies. Causative agents include the insulin molecule, insulin dimers, pro-insulin-like substances or additives in insulin preparations.<sup>7</sup> Studies have shown that patients can be allergic to both animal and human insulins.<sup>8,9</sup> Insulin allergy is a risk when switching species type or brand of insulin and can only be anticipated by skin tests or a patient's initial response after multiple doses of the new insulin.

Hypoglycemia is a common and potentially serious complication of insulin therapy. In the Diabetes Control and Complication Trial (DCCT) 9.8% of subjects in the standard treatment group had severe hypoglycemia during the twelve months of study.<sup>10</sup> Studies have shown between 2% and 7% of deaths in insulin-dependent diabetics were caused by hypoglycemia.<sup>11</sup> There have been reports which describe an increased frequency of hypoglycemia with human insulin as compared to animal species insulin.<sup>12,13</sup> Impaired recognition of hypoglycemia has been reported in patients whose therapy is changed from animal to human insulin.<sup>14,15,16</sup> Data from Berger *et al* demonstrated a difference in the initial symptoms of hypoglycemia between porcine and human insulin.<sup>15</sup> Initial symptoms with porcine insulin were more often adrenergic (*i.e.*, sweating, hunger) versus "neuroglycopenic" (*i.e.*, anxiety, unrest, confusion, dizziness, difficulty with concentration, paraesthesia, visual disturbances) with human insulin. Results from the Diabetes Complication Study showed that "human insulin use does appear to be

associated with reduced awareness of hypoglycemia in those whose blood glucose is relatively poorly controlled."<sup>16</sup>

---

***Allergic reactions to insulin appear to be caused by insulin antibodies. Patients can be allergic to both animal and human insulins....***

---

Based on the information presented, switching the brand or species type of insulin may cause a change in the kinetics, immunogenicity and/or side effect profile of a given patient. Transferring patients from one type of insulin formulation to another may create glycemic instability and subject the patient to an increase or decrease in the incidence of local or systemic allergy, serum insulin concentration, and serum antibody concentration. Transferring patients from one formulation to another may require a dosage adjustment and therefore should be done under medical supervision.

#### **Legal Liability Issues**

The issue of legal liability for pharmacists who sell insulin products cannot be ignored. In fact, the pharmacist may be confronted with more potential legal risks by selling insulin than by dispensing prescription drugs. This greater potential arises because of the

complex clinical implications of the product, the fact that there are so many different insulin products and the fact that it is an over-the-counter product for which patients often rely upon the pharmacists' professional judgement and advice.

#### **Theories of Liability**

Legal liability risks to a pharmacist may primarily arise from two theories: negligence and breach of warranty. Under negligence, a patient may sue a pharmacist for failing to act (or not act) as a reasonably prudent (or ordinary) pharmacist would have acted under the circumstances. Establishing negligence requires a patient to prove: 1) that the pharmacist owed the patient a duty; 2) that the pharmacist breached that duty because of substandard act or omission; 3) that the substandard act caused the injury; and 4) the injury and amount of damages. The breach of warranty theory arises from the fact that the sales transaction constitutes a contract between the pharmacist and the patient. Under this therapy a patient may sue because of an oral, written or even implied assertion or promise by the pharmacist which the patient relies upon to his or her detriment.

#### **Potential Liability Situations**

Liability can result from selling the patient the wrong insulin. For example, in one case a pharmacist was determined negligent when he

*Continued on page 15....*

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sold the patient Lente insulin instead of Semilente insulin, which the patient had requested.<sup>17</sup> Breach of warranty would have been equally applicable, since the patient could have established that the pharmacist breached the terms of the contract by supplying the wrong product which caused the patient's injury. In a similar case, a pharmacist was liable under negligence for selling the patient R-U-100 insulin instead of the N-U-100 insulin requested.<sup>18</sup>

Issues of liability may also arise because of the pharmacist's advice or lack of advice to the patient. For example, assume a patient wishes to switch insulins and consults with the pharmacist about the switch. Under either theory of liability the pharmacist has a duty to render proper professional advice. That advice at a minimum should include reference to the warning statements which are required on insulin labeling which provide: "Warning: Any change of insulin should be made cautiously and only under medical supervision." and "Changes in refinement, purity, strength, brand (manufacturer), type (regular, NPH, Lente, etc.), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage."

Thus, the pharmacist should never assume a switch in insulin is minor, even a switch from the same brand of human semi-synthetic insulin to human rDNA insulin. The patient should always be advised of the warning and the need to consult a physician.

The liability of a pharmacist becomes less clear when the patient



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does not seek the pharmacist's advice, but purchases the insulin at the pharmacy. For example, a patient

who has been using Novolin human semi-synthetic insulin purchases Novolin human rDNA insulin, not

realizing that the company had discontinued the semi-synthetic insulin and phased in the rDNA insulin. In its literature the company stated only that no change in dosage or daily regimen should be required. It may be possible that in some patients a change will be required. Although the risk of liability to the pharmacist is low, risk does exist and it is a simple exercise in risk management and professional service to advise all patients of this change in Novolin. In any situation where the pharmacist knows, or has reason to know that a patient may be switching insulin, the pharmacist should warn the patient, regardless whether the patient seeks the pharmacist's advice.

### Conclusion

The pharmacist is in the unique position of interacting with diabetic patients on a daily basis. Pharmacists should make every effort to become knowledgeable about the different insulin products and supplies available to patients and exercise that knowledge through patient counseling. Patients should be educated on the signs, symptoms and treatment of hypoglycemia and should be cautioned not to switch insulin without medical supervision. ■

### Authors

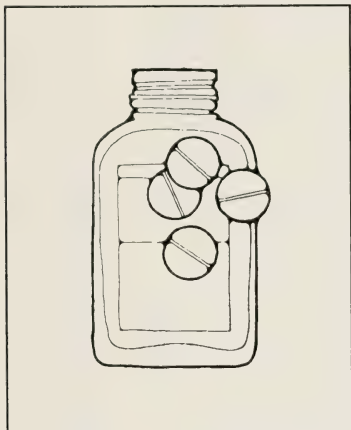
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# The Controversy Continues: FDA & Pharmacy

*Shelly Schluter, Executive Director, P2C2*



Pharmacies have been an integral part of American health care for many years. For decades, pharmacies have compounded medications, pursuant to physicians' prescriptions, for their patients.

The task of regulating pharmacy compounding has been performed by the states. The federal government has not intervened. Until now.

On March 16 of this year the Food and Drug Administration (FDA) unveiled Compliance Policy Guideline (CPG) 7132.16. This document imposes significant new restrictions on compounding by pharmacists.

The CPG identifies nine prohibited categories of conduct; deviation from any element places the pharmacist at risk of FDA enforcement action. These nine categories are rather vague. Employing such terms as "inordinate" and "regularly", the CPG forces pharmacists to guess what behavior will be deemed objectionable by FDA. The consequences of guessing wrong can be enormous. During a recent speech, one of FDA's top enforcement officials said, "As for retail pharmacies/pharmacists who will continue to perform one or more of the nine actions listed in the CPG, and thus manufacture unapproved new drugs, they should know that they may be prosecuted."

Not surprisingly, the CPG has been rather controversial. Many pharmacy groups have asked FDA to clarify its policy and explain what the CPG means. Thus far, no clarification has been offered.

This intolerable situation was entirely avoidable. Professionals and Patients for Customized Care (P2C2), a non-profit organization formed to protect the rights of pharmacists, believes that a federal law, the Administrative Procedure Act, required FDA to solicit comments before issuing the CPG. In any event, P2C2 sent a letter to FDA last December asking for a chance to discuss any new guidelines before they were issued. Other organizations, including the American Pharmaceutical Association, also requested FDA to open a dialogue with pharmacists before announcing a new policy.

FDA rebuffed each and every request. Instead, FDA chose to issue the CPG unilaterally. In a letter sent to P2C2 three months after the CPG was issued, FDA essentially said it felt there simply was no need for any input from pharmacists on how they should be regulated and said, "FDA does not think it relevant to distinguish between compounding and manufacturing (they both produce a drug) or to define terms;".

The CPG is bad enough. Yet FDA had gone even further: it now claims that all compounded drugs are illegal. The CPG itself says compounded drugs are not exempted from the new drug provisions of the Federal Food, Drug and Cosmetic Act (the Act). This means FDA believes each compounded drug must be the subject of an approved new drug application (NDA). It is estimated that it takes ten years and \$200 million to get an NDA. But without an NDA, according to FDA, the compounding pharmacist has broken federal law.

FDA's position was even more clearly stated in a warning letter sent to a pharmacist this June. An FDA district director wrote, "a drug product compounded in a pharmacy without FDA's approval is an unapproved new

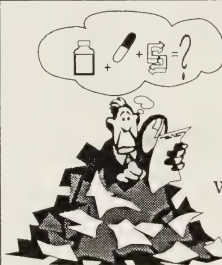
drug subject to all the provisions" of federal law. Violating these provisions can lead to severe penalties: product seizure, court injunction and criminal prosecution.

At the end of August, FDA made bolder attempts to restrict the pharmacists' ability to compound. The FDA issued warning letters to pharmaceutical supply companies. One letter said the supply company is in violation of federal law because the chemicals they supply to pharmacists "are drugs offered for use by registered pharmacists in compounding prescriptions." The letter further stated, "the compounded drugs are regarded to be new drugs within the meaning of Section 201(p) of the Act, and no New Drug Applications have been approved for these compounded drugs." The chemicals the FDA charged to be in violation of the act are: progesterone, metaproterenol sulfate, progesterone wetttable, sucralfate powder, prednisone, cromolyn sodium and albuterol sulfate. In another letter to a chemical supply company, FDA gives a list of the only chemicals that the FDA says can be legally sold to pharmacists for compounding. The list includes: bacitracin, bacitracin zinc, erthromycin, hydrocortisone, hydrocortone bitartrate, neomycin sulfate and polymyxin B sulfate.

Historically, the pharmacy profession has been well respected by the public and has an excellent history of safety. We strongly believe that FDA's intrusion into this area was unnecessary and unwarranted. We reject FDA's assertion that a pharmacist commits a federal crime every time he or she compounds and that a chemical company is in violation of federal law because it supplies chemicals to pharmacists who compound. And we are distressed that FDA rejected all efforts to develop its new pharmacy policies without guidance from the individuals most affected -- the pharmacists of America. We therefore urge FDA to withdraw its CPG and its statements that compounded drugs are illegal, and initiate a dialogue with the entire pharmacy community.

## About the Author

Shelly Schluter is the executive director of Professionals & Patients for Customized Care (P2C2). P2C2 is an organization consisting of pharmacists, physicians and patients, who are actively working to keep FDA regulations out of the practice of pharmacy. If you have any questions, or would like to become a member of this organization to help defer the cost of the lawsuit for all of pharmacy, please contact Shelly at the P2C2 office 713/933-8440, or write to: P2C2, P.O. Box 1365, Sugar Land, Texas 77487.



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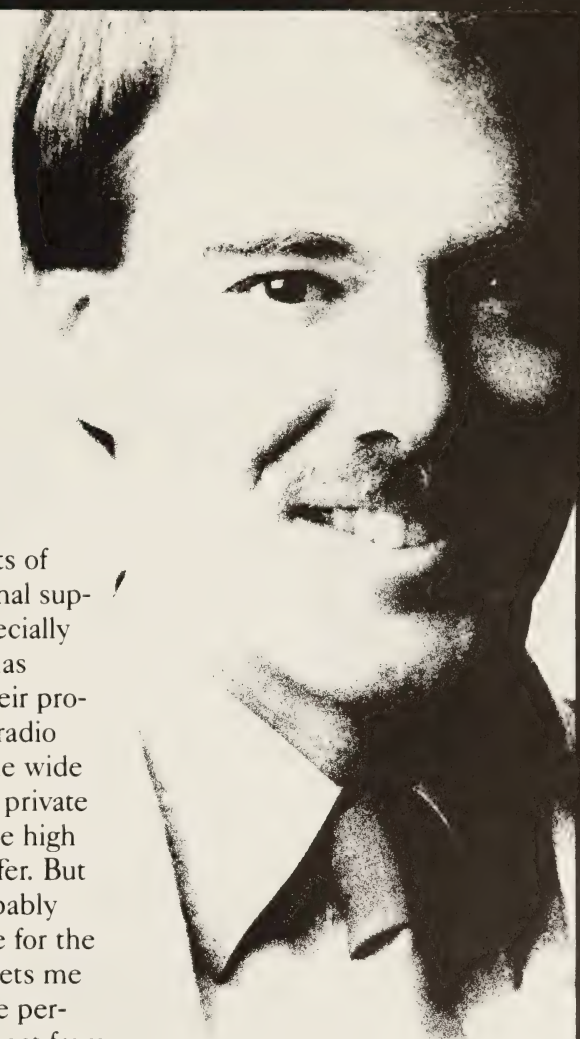
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# Privacy, Prescriptions, and Police

David B. Brushwood, J.D.



A lawsuit was filed in Ohio by physicians, patients and a pharmacist, against six local communities which had set up a system to collect and analyze prescription records. The program's alleged objective was to use pharmacy records to obtain data on the diversion of controlled substances from legitimate channels to illicit channels, either from patients obtaining multiple prescriptions of the same drug from multiple physicians, or excessive doses of the same drug being filled in multiple pharmacies within the six-community area. The data were obtained by having both uniformed and non-uniformed police personnel enter community pharmacists and record the names of patients receiving certain controlled substances. The data were then transferred to floppy disks, centralized at the police station in one of the communities, and evaluated prior to erasure of the disks. The plaintiffs in the case contended that the communities were violating the right of privacy and the prohibition against unreasonable searches and seizures found in the United States and Ohio Constitutions. The lower court ruled against the plaintiffs, and in favor of the communities, and the plaintiffs appealed.

The first issue on appeal was whether the system violated the Constitutional right to privacy. The court initially noted that there are two types of privacy rights. One type is the individual interest in avoiding disclosure of personal matters. This is usually called "negative privacy," because it prevents someone from interfering with another person by publicly disclosing private facts or invading the other person's seclusion. The other type of privacy right is the interest in independence in making certain kinds of important decisions. This is usually called "positive privacy," because it requires that someone do something for another person, to assure that the other person is given the opportunity to make an autonomous decision about himself or herself.

The plaintiffs argued that the system of collecting data on controlled substances prescriptions violated the negative privacy right because there were too few limits on improper use of the information, and that too many employees of the police departments had access to this very personal information. The court disagreed, noting that while there existed a threat of unauthorized disclosure by police to others who had no reason to need the information, that threat itself was insufficient that unauthorized disclosure would inevitable occur, thus disagreeing with the position advocated by the plaintiffs.

The plaintiffs also argued that the system violated the positive right of privacy, because it posed a threat to patient autonomy in making health care decisions. According to the plaintiffs, patients might not choose the most effective therapy if it involves the use of controlled substance, due to fear that the police will be suspicious of the patient's conduct. However, the court did not see anything in the system that placed unacceptable burdens on patient's freedom of choice.

Turning to the unreasonable search and seizure issue, the court first noted that pharmacists have no right to resist the system, because state law permits the routine inspection of pharmacy records, and this activity is necessary to address a major social problem.

*Continued on page 22....*

# Dickinson's Pharmacy

Jim Dickinson

*Drop by drop.* Many a pharmaceutical preparation owes its efficacy to the addition of a drop at a time.

So it is with pharmaceutical causes. But in this age of ready-prepared medications, the patience to persist, drop by drop, in a cause is often missing.

I am learning the value of persistence and of a drop at a time in my four-year quest at the Food and Drug Administration to have mail-order "pharmacy" regulated by that agency. (I always put inverted commas around "pharmacy" when it follows the term "mail-order," not to cause offense to those noble and well-educated pharmacists who toil in mail-order prescription factories, but to keep alive my view that what goes on in those facilities is not real-world pharmacy -- not that I have ever been inside one, because all my requests for admittance have been sneeringly rejected by their owners. "Do you blame us, with your reputation?" some have replied -- to which I say, "You must be terribly scared!")

FDA has agreed to re-examine my 1988 petition, which it rejected in late 1990, on the basis of my drop by drop persistence, based on the supreme importance of this cause.

Since the original petition was denied -- primarily on the grounds that the states were doing a good job in regulating mail-order prescription mills -- I have presented new evidence to the agency, one drop at a time.

One "drop" was University of Montana law professor Gregory Monro's *Journal of Legal Medicine* article last fall that described the present regulatory scheme for interstate mail-order prescriptions (i.e., pick your own state to operate in

and ignore all the other states' laws) as "courting a future disaster."

Another "drop" was the mail-order industry's American Managed Care Pharmacy Association response to Monro -- it said that to comply with "multiple and overlapping state requirements is burdensome to the point of being economically prohibitive." For an industry so awash with money and surplus profits that it is the perpetual darling of Wall Street, that confession rang alarm bells all over FDA.

Yet another "drop" was FDA's investigation of interstate pharmacy "compounding" operations that it viewed as actually amounting to illicit generic drug manufacturing operations, because of the huge volumes involved. Speed and volume, of course, are what make mail-order "pharmacy" so dangerous -- no different in that respect than the contested "compounding" operations.

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***If mail order is as dangerous as pharmacy believes, publicity from the FDA's complaint files can help bring a "level playing field" to the pharmacy benefits business...***

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Now I'll admit that FDA is barking up the wrong tree on the compounding issue -- most of the pharmacies it sent warning letters to were doing only honest, traditional compounding. By setting limits on the practice of pharmacy just to catch a few illicit "manufacturers" disguised as high-tech pharmacies, FDA is

using a sledge hammer to swat a fly (and breaking up the house of pharmacy is the process).

But there may be a silver lining in FDA's clumsy interest. It has seen the dangers of unregulated interstate prescription shipments in a new light.

You might ask: Aren't you counting your chickens before they're hatched? Just taking a second look doesn't mean FDA will regulate interstate mail-order prescriptions.

To which I'd say -- But it's another "drop." Drop by drop, we'll get there. If FDA turns us down this time, it will likely do so in a manner that will open new doors, so we can come back again.

And then there's the question many ask -- Do we want the feds in pharmacy at all, even if it's only to regulate mail-order? You know, toe in the door, and soon they'll take over other things....

It's a shrinking world. In Europe, the national governments are handing over their powers to the ECC. Some even see a World Government in the future.

I don't like any of this any more that you do -- and I'm skeptical that it will ever really come about. But we do have to bend a little in the tide of events that trend this way and that.

The tide in pharmacy has been toward mail-order for maintenance drugs. The economics don't make sense, because waste overcomes the paper savings -- but to quote an old huckster from the turn of the century, "there's a sucker born every minute." There seems to be an unlimited supply of new health benefits "suckers" out there who will buy the mail-order savings mirage.

*Continued on page 22....*

## Dickinson's Pharmacy

*Continued from page 21...*

The worst thing is that often they fall for the mirage before community pharmacy groups are even aware the plan is hunting for price breaks.

In this high-speed, high-volume world a modest FDA requirement that interstate mail-order prescription factories maintain complaint files for FDA inspection, and that they directly report to FDA any error that escapes into the mail, is a small price to pay for a necessary element of consumer protection.

If mail-order is as dangerous as we believe it is, publicity from FDA's many discoveries from mandatory complaint files and direct reporting will help bring a "level playing field" to the pharmacy benefits business, which increasingly disadvantages community pharmacy now.

So if you know of a mail-order error, tell FDA about it, referencing Petition No. 91P-0414/CP, Dockets Management Branch, FDA-HFA 305, 12420 Parklawn Drive, Rockville, Maryland 20857.

One drop at a time, we'll fill FDA's bucket of concern! ■

This feature is presented on a grant from Dickinson's Pharmacy -- *The Independent Voice*, a professionally stimulating monthly newsletter available for \$45 a year plus your retail pharmacy's label from Ferdic, Inc., PO Box 367, Las Cruces, NM 88004-0367.

## Privacy, Rx's and Police

*Continued from page 20...*

Likewise, physicians and patients cannot legally prevent the system from operating, because although it is a search, it is a reasonable search, and only unreasonable searches are forbidden by the Constitution.

In vigorous dissent, three of seven justices described the system as "totally open-ended," permitting "what could only be described as a fishing expedition." The dissenters pointed out that all prescriptions were being scrutinized in an attempt to detect abuse of only a few controlled substances. This minority opinion expressed the view that patients have a right to privacy that should protect them from such a system.

Nevertheless, the majority prevailed, and the system was judicially approved as constitutional. *Based on: Stone v. City of Stowe, 593 N.E. 2d 294 (Ohio 1992)* ■

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No. 24

## WHAT'S IN A NAME?

The USP Drug Product Problem Reporting Program (DPPR) has received reports from pharmacists across the nation indicating problems with similarly named products. Some drug names look alike when they are handwritten. Others sound alike in pronunciation and this audible similarity may be enhanced by geographical accents in various regions of the United States. A brand name may look or sound similar to another brand name, or a brand name may be similar to the nonproprietary name of another product. Concerns are heightened where similarly named products have comparable strengths and dosage forms. Some reporters suggest changing product names to alleviate these problems, however, this solution is not usually so simple. Since drug products have chemical names, compendial names (USP or NF), nonproprietary (generic) names, and proprietary (brand) names, it may be of interest to know more about what is behind a product name.

### USP REVIEW

The **chemical name** of a drug provides precise information concerning the chemical structure of the drug substance. International standards or guidelines have been developed for the purpose of naming new chemical entities. Although chemical names provide scientific personnel with a complete, precise, unambiguous description of the substance, they do not constitute a concise, convenient designation that meets the day-to-day needs of the pharmacist, physician, patient, and others involved in functions relating to pharmaceuticals. Nonproprietary names better serve these needs.

New **nonproprietary** (generic) drug names are formulated through the United States Adopted Names (USAN) program. The USAN program is the specifically organized effort in the United States directed to producing simple and useful nonproprietary names for drugs while the drugs are still in the investigational stages. The American Medical Association, the U.S. Pharmacopeial Convention, and the American Pharmaceutical Association jointly sponsor the USAN program with representation from the Food and Drug Administration (FDA). A firm or an individual, who has developed a substance of potential therapeutic utility to the point where there is a distinct possibility that it will be marketed in the United States, usually originates a proposal for a USAN.

A nonproprietary name identifies a substance and serves as a designation that may be used without restriction by the public, both lay and professional. Teaching in pharmacy and allied health care professions requires a common designation, especially for a drug that is available from several sources. Nonproprietary names greatly facilitate communication between health care professionals, and most journals demand their use. Finally, federal law obligates the manufacturer to use the "established" nonproprietary name in advertising, labels, and brochures.

The value of designating each drug by one nonproprietary name is obvious: it achieves simplicity and uniformity in drug nomenclature. The USP Committee of Revision gives consideration to the adoption of the USAN, if any, as the **official** title (name) for any compound that attains compendial recognition.

A **proprietary** name for a drug product is chosen by a firm for marketing purposes, usually early in the approval process. The proprietary name is considered part of the labeling by the FDA. The labeling that accompanies a new drug product is approved by the FDA with the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) for the product. Once the labeling is approved by the FDA, a firm may be required to submit a supplement to its NDA or ANDA if a change in the proprietary name is sought. According to FDA's labeling regulations under 21 CFR 201.10(c)(5), the labeling of a drug may be considered misleading when the "designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient."

While a change in proprietary and nonproprietary names for drug products is not common, it does occur. Reporting confusing or similar names is important to create an awareness among industry, regulatory bodies, health care professionals, and the compendia. This awareness may lend assistance in choosing the best name to serve the purposes of all parties involved.

Health care professionals should take precautions necessary to avoid product mix-ups for similarly named products in the marketplace. Some suggestions include:

- Printing or typing prescriptions, as opposed to handwritten orders, to make them more legible.
- Spelling the drug name for orders given verbally to help avoid misunderstandings.
- Obtaining patient information, such as diagnosis and concurrent medications, to help determine if the drug order is likely to be part of the patient's drug regimen.
- Patient counseling to avoid mix-ups of similarly named products from occurring.

To report problems with drug products, or for further information, call the USP DPPR Program at 1-800-638-6725.

Issued 1/92



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# Drug Information Questions

## *Treating Common Fungal Infections*

Mehdi Azadi, Babette S. Prince, Pharm.D., UMAB Drug Information Center

This article provided under a grant-in-aid from **Glaxo**

### **Drug Information Request**

What treatments are available for common fungal infections including athlete's foot, jock itch and nail infections?

### **Response**

Today's pharmacists are faced with numerous questions about fungal infections from their patients. They are frequently asked to recommend OTC preparations for the treatment of various types of fungal infections including athlete's foot, jock itch and vaginal infections.

Fungal infections are among the most common cutaneous infections.<sup>1</sup> They vary in presentation and may present as single or multiple lesions with mild scaling or deeply inflamed nodules. Infections of the skin, hair and nails are generally caused by three genera of fungi: *Trichophyton*, *Microsporum* and *Epidermophyton*. Species of *Candida* may also be involved. Fungal infections are usually superficial and involve only the outermost layers of the skin; however, they can be much deeper when the affected area is covered with heavy hair, due to hair follicle penetration.<sup>1,2</sup>

Superficial fungal infections are classified as dermatophyte (tineas, ringworms) or yeast infections. Among the dermatophytes, *tinea pedis* (Athlete's foot) is the most prevalent cutaneous fungal infection in humans.<sup>2</sup> It is characterized by scaly rashes, maceration, hyperkeratosis, pruritus, malodor and a stinging sensation of the feet. More severe cases may present as severe inflammation and exudative lesions, which may lead to denudation and fissuring. *Tinea pedis* occurs in warm, moist environments and is prevalent in the adult male population.<sup>3,4,5</sup>

*Tinea cruris* (eczema marginatum, jock itch, dhobie itch, ringworm of the groin) unilaterally or asymmetrically involves the groin, inner thighs and buttocks, and presents itself as multiple discs or rings. The pruritic lesions have specific elevated margins that are more inflamed than the center of the lesion. Small vesicles are sometimes found at the margins. The lesions vary in color from bright red to brown, and may be scaly. This infection is most commonly transmitted by careless exchange of clothing or

towels.<sup>3,4,5</sup>

*Tinea corporis* (ringworm of the body) involves the glabrous (smooth and bare) skin and is characterized by small, circular, erythematous, scaly lesions which mainly affect the face, shoulders, or arms. Most lesions have prominent edges that may contain pustules or follicular papules. The center of the lesions is less inflamed and more scaly. The incidence of this infection is high among populations who live in humid environments.<sup>3,4,5</sup>

*Tinea unguis* (Onychomycosis, ringworm of the nail) is a fungal infection that involves the finger or toe nails. Toenail involvement is common in longstanding *tinea pedis*; fingernail involvement is less common. As the infection progresses, the nail becomes discolored, thickened, distorted, lusterless and broken. The nail plate becomes separated, and the nail may be destroyed.<sup>4</sup>

*Tinea capitis* (ringworm of the scalp) is characterized by small, scaly, semi-bald grayish patches of the scalp, with stumps of hair broken off just above the surface. A raised, inflamed, boggy granuloma (kerion) may also occur and is followed shortly by healing. This infection mainly affects children and is very contagious. Occasionally parents of the infected children can develop glabrous infections once they come in contact with the infected scalp.<sup>3,4,5</sup>

*Tinea barbae* (ringworm of the beard area) is rare. Infections of this area are usually bacterial and need to be confirmed by microbiologic study.<sup>2,3,5</sup>

Topical agents are commonly used for the treatment of minor superficial fungal infections. Success of therapy increases if the lesions are small, and are contained in a limited non-hairy area.<sup>2,3</sup> Today, there are over 34 OTC antifungal agents and 47 legend products available on the US market. These preparations contain various ingredients that have antifungal and antibacterial properties. Table 1 lists various products and their indications.

If the lesions are extensive or involve the nail (*Tinea unguis*), or scalp (*Tinea capitis*), topical therapy is generally ineffective and systemic therapy should be considered (Table 2). Oral therapy should be used in *Tinea pedis* for chronic infections or for prevention of acute exacerbations. Oral therapy may also be used in

Drug	Class	Indication	Duration of Therapy	Comments
Ciclopirox olamine (Loprox)	Broad spectrum antifungal	Tineas pedis, cruris, corporis, versicolor, and candidiasis	Clinical improvement usually seen within first week, except tinea versicolor which is 2 weeks	Reevaluate the diagnosis if no improvement seen within 4 weeks
Triacetin (Fungoid tincture, Fungoid)	Broad spectrum antifungal and antimicrobial	Onychomycosis, tineas pedis, cruris, corporis, monilial impetigo and dermatitis	1 to 4 weeks  Onychomycosis requires several months of treatment	Spray and tincture are only for treatment of onychomycosis. Notify physician if no improvement after 4 weeks.
Econazole (Spectazole)	Antifungal Imidazole	Tineas pedis, cruris, corporis, versicolor, cutaneous candidiasis	2 weeks for tineas cruris, corporis, versicolor and candida infection 1 month for tinea pedis	Notify physician if no improvement after this time.
Ketoconazole (Nizoral)	Broad Spectrum Antifungal	Cream -- tineas corporis, cruris, versicolor, cutaneous candidiasis Shampoo -- seborrheic dermatitis	2 weeks for tineas corporis, cruris, candida 4 weeks for seborrheic dermatitis	
Nystatin (Mycostatin, Nilstat)	Tetraene macrolide	Vaginal candidiasis (cutaneous and chronic) Mucotaneous candidiasis	Apply affecto affected area 2 to 3 times a day until healing. Treatment for 2 weeks is usually sufficient.	Avoid occlusive dressings
Terconazole (Terazol)	Antifungal Triazoles	Vaginal candidiasis	3 to 7 days	Available in cream and suppository form

**Topical Antifungal Agents**<sup>3,6,7,8,10</sup>  
**Table 1**

Drug	Class	Indication	Duration of Therapy	Comments
Undecylenic acid (Desenex, Cruex)	Antibacterial Antifungal Fungistatic	Tineas pedis, cruris and for ringworm	2 to 4 or more weeks	Consult physician over 4 weeks and if patient is diabetic
Clioquinol (Vioform)	Antibacterial Antifungal Imidazole	Tinea pedis	< 1 week	May irritate skin
Tolnaftate (Tinactin)		Tineas pedis, cruris, corporis, versicolor	2 to 3 weeks	Need 4 to 6 weeks of treatment if skin has thickened
Haloprogin (Halotex)	Synthetic Antifungal	Tineas pedis, cruris, corporis, manuum, versicolor	2 to 4 weeks	May take up to 4 weeks
Naftifine (Naftin)	Allylamine Broad Spectrum Antifungal	Tineas corporis, cruris, pedis	1 to 4 weeks after symptoms have subsided	6% of dose is absorbed
Oxiconazole (Oxistat)	Broad Spectrum Antifungal Imidazole	Tineas pedis, cruris, corporis	2 weeks for tineas corporis and cruris 1 month for tinea pedis	Review diagnosis if no clinical improvement
Sulconazole (Exelderm)	Broad Spectrum Antifungal Imidazole	Tinea pedis (cream only), tineas cruris, corporis, versicolor	4 weeks for tinea pedis 3 weeks for tineas cruris, corporis and versicolor	Consult physician after 4 to 6 weeks for alternate diagnosis

**Topical Antifungal Agents**<sup>3,6,7,8,10</sup>  
**Table 1**

Drug	Class	Indication	Duration of Therapy	Comments
Ketoconazole (Nizoral)	Broad Spectrum antifungal	Severe recalcitrant dermatophyte infections not responding to topical treatment or oral griseofulvin or in patients unable to take griseofulvin. Unlabeled uses include onychomycosis, tinea versicolor, pedis, corporis, cruris, capitis; and vaginal candidiasis.	Minimum 4 week treatment	
Griseofulvin (Fulvicin Grifulvin Grisactin Gris-Peg)	antibiotic	Tinea corporis, pedis, barbae, capitis, unguim	Tinea capitis 4-6 weeks Tinea corporis 2-4 weeks Tinea pedis 4-8 weeks Tinea unguim 4-6 months	Treatment until organism is completely eradicated.

**Oral Antifungal Agents<sup>3,6,7,8,10</sup>**  
**Table 2**

Tinea corporis and Tinea cruris for extensive or resistant infections.<sup>2,4,6</sup>

Griseofulvin, an antibiotic derived from a species of *Penicillium*, is first line therapy for treatment of these infections. Griseofulvin is deposited in the keratin precursor cells, which are gradually sloughed off and replaced by non-diseased tissue. The dose is 500 mg (microsize) or 330-375 mg (ultramicrosize) daily for tinea corporis, cruris and capitis. For tinea pedis and unguim, the dose is 0.75-1 g microsize (660-750 mg ultramicrosize) per day in divided doses. Treatment for tinea unguim

must be continued until the nail has regrown completely. Griseofulvin is used as a microsize form in conjunction with fatty meals to increase its absorption through the gastrointestinal tract. Since the microsize form has higher surface area, the bioavailability is improved. The most common adverse effects associated with its use include headache, fatigue, dizziness, nausea and vomiting.<sup>2,4,7,8,9</sup>

Ketoconazole is indicated for severe recalcitrant cutaneous dermatophyte infections not responding to topical therapy or griseofulvin, or in patients that are

unable to take griseofulvin. It has been used successfully to treat tinea unguium, corporis, cruris, pedis (200-400 mg/day) and capitis (3.3-6.6 mg/kg/d).<sup>2,4,7,8,9</sup>

Vulvovaginal candidiasis is another superficial fungal infection that is quite common. It is believed that approximately 25% of women in their childbearing years will develop a vaginal infection caused by candida albicans. Some risk factors for this infection include obesity, use of hormonal contraceptives, poor vaginal hygiene, pregnancy, diabetes and drugs, such as corticosteroids, antineoplastics and antibiotics. The clinical manifestations of this infection include thick curd-like discharge from the vagina with severe pruritus of the vulva.<sup>1,2,3,10</sup>

Current treatment modalities for superficial vaginal candidiasis include miconazole, clotrimazole (OTC products), terconazole, and nystatin (prescription products). The recommended intravaginal dose of clotrimazole is a 100 mg vaginal tablet at bedtimes for seven nights or two 100 mg tablets intravaginally for 3 nights. In addition, one may also use an applicatorful of cream at bedtime for seven to fourteen nights. The dose of terconazole is one applicatorful intravaginally every night for three to seven consecutive nights (dependent on whether the 0.8% or 0.4% cream is used). Suppositories are also available. The intravaginal dose of miconazole is one suppository intravaginally at bedtime for three days or one applicatorful of cream at bedtime for seven days. The intravaginal dose of nystatin is one tablet (100,000 units) daily for two weeks.<sup>1,2,3,10,11</sup>

Appropriate assessment of the patient's condition is crucial for any recommendation. The pharmacist should be able to recognize fungal infections based on patient history and appearance of sequelae. Pharmacists need to familiarize themselves with the OTC antifungal products and be able to recommend appropriate products based on a patient's individual needs. A follow up visit for the patient should be scheduled in order to assess outcome of treatment. The pharmacist must also be able to recognize when appropriate patient referral to their physician is needed. ■

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## Continuing Education Quiz

November 1992 -- Diabetes Mellitus

This month's questions are taken from the articles in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by April 30, 1993. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

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Is this program used to meet your mandatory CE requirements?  
Was this issue/article useful to you in your practice?

☐ Yes      ☐ No  
☐ Yes      ☐ No

1. The Diabetes Care Program through Maryland Medicaid provides:
  - a. Additional services and products to diabetics
  - b. Is voluntary
  - c. Covers all medications, not just antidiabetics
  - d. All of the above
2. The new product available through the Diabetes Care Program which most affects pharmacists is:
  - a. Providing a meter to individuals treated with insulin
  - b. Providing coverage for medications
  - c. Providing coverage for specialized footwear
  - d. Providing coverage of meters to individuals treated with oral agents.
3. Individuals enrolled in the Diabetes Care Program are:
  - a. Assigned a primary care provider who coordinates the medical care for the individual
  - b. Can seen any physician or specialist they choose
  - c. Are limited to the number of visits per year
  - d. None of the above
4. Metformin may be most useful in the treatment of:
  - a. Hyperglycemia of any etiology
  - b. Insulin dependent diabetes
  - c. Type I diabetes
  - d. NIDDM
5. Metformin can be classified as:
  - a. Hypoglycemic agent
  - b. Antihyperglycemic agent
  - c. An insulin substitute
  - d. A hyperglycemic agent
6. In addition to lowering blood glucose levels, metformin has the potential to promote:
  - a. Weight loss
  - b. Lower LDL and VLDL lipoproteins
  - c. Increased HDL levels
  - d. Antiatherogenic processes
  - e. All of the above
7. The maximum daily dose of metformin is:
  - a. 850 mg at breakfast
  - b. 500 mg twice daily
  - c. 1700 mg
  - d. 3 grams
  - e. There is no maximum daily dose of metformin
8. When used in combination with insulin, metformin may have the potential to:
  - a. Lead to insulin resistance
  - b. Decrease daily insulin requirements
  - c. Increase daily insulin requirements
  - d. Potentiate hypoglycemic episodes
9. The most common side effect of metformin is:
  - a. Lactic acidosis
  - b. Renal insufficiency
  - c. Gastrointestinal
  - d. Hepatic disease
10. Patients with the following disease states may be contraindicated to receive metformin therapy:
  - a. Renal impairment
  - b. Hepatic disease
  - c. Cardiac insufficiency
  - d. History of lactic acidosis
  - e. All of the above

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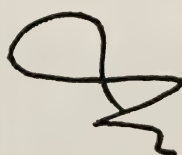
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Frank McGinity, P.D.

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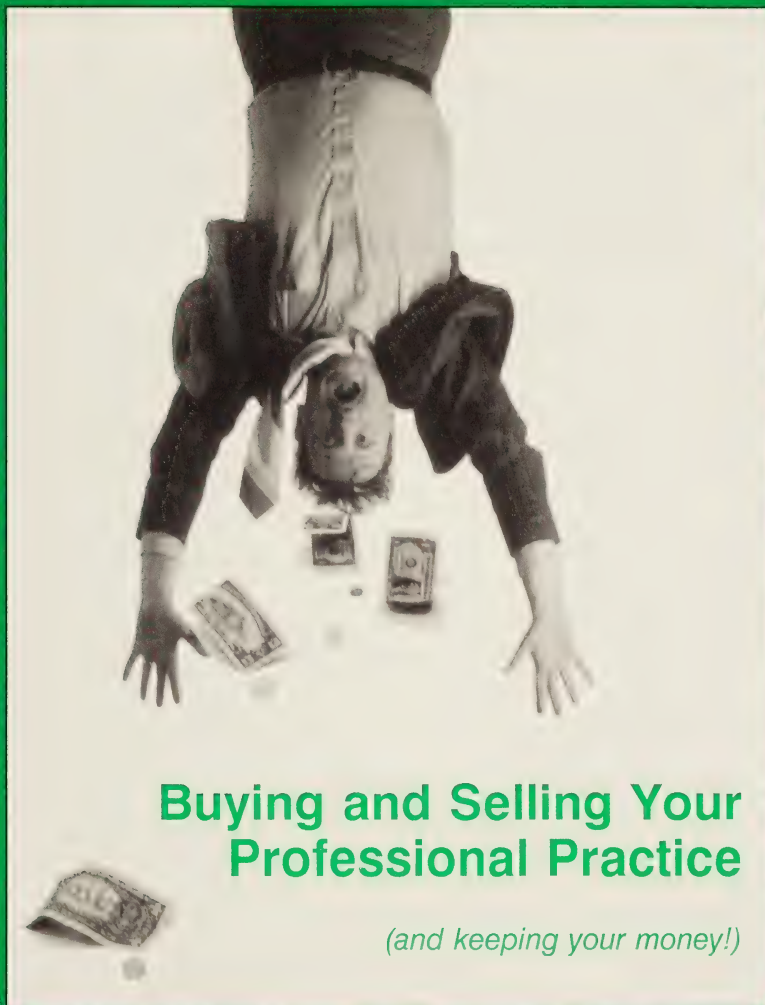


# The Maryland Pharmacist

VOL. 68

December, 1992

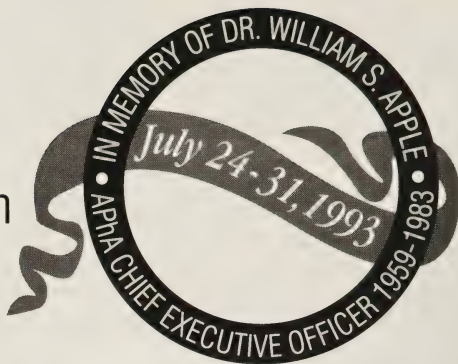
No. 12



**Buying and Selling Your  
Professional Practice**

*(and keeping your money!)*

# The American Pharmaceutical Association/SmithKline Beecham **Community Pharmacy Management Program**



**T**he APhA/SmithKline Beecham Community Pharmacy Management Program is designed to advance pharmacy practice by improving the management knowledge and skills of community pharmacy practitioners. This seven-day executive level training program is sponsored by APhA and supported through an educational grant from SmithKline Beecham Pharmaceuticals. This year's program will include topics such as:

- Financial and Economic Trends in Pharmacy
- Strategic Planning
- Marketing the Community Pharmacy
- Computerized Data Management Systems
- Pricing/Reimbursement Policies
- Communicating with Patients
- Leadership
- Implementing Personnel Policies
- Identifying Niche Markets
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July 24-31, 1993  
The University of Wisconsin  
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To apply for the 1993 program, request an application form from APhA. The APhA/SmithKline Beecham Community Pharmacy Management Program will give you the information you need to advance your practice and your career. Applying and attending is one of the wisest investments you can make of your time. Tuition, transportation, and room and board for all program participants are provided by APhA.

**Application Deadline:**  
February 15, 1993

*"From start to finish, the program was exceptional. In addition to being exposed to a terrific, high quality curriculum, I was equally inspired by associating with my fellow participants."*

**Mary E. Enzweiler, 1992 Graduate**  
Reynolds Pharmacy  
Augusta, KY

*"The program made me more knowledgeable about the economic, administrative, and managerial aspects of community pharmacy. I have begun to incorporate that knowledge into my practice, as well as share it with my colleagues."*

**Daniel R. Witham, 1992 Graduate**  
Walgreens Pharmacy  
Portage, MI

*"The interaction among the participants throughout the week provided a format for the exchange of ideas and information that proved to be as educational as the formal program itself."*

**Thomas J. Croce, Jr., 1992 Graduate**  
Jefferson Apothecary  
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**For additional information and an application form  
contact Ann Sullivan at APhA 1-800-237-2742**

# The Maryland Pharmacist

The Official Journal of the Maryland Pharmacists Association

650 West Lombard Street, Baltimore, Maryland 21201-1572

December 1992

Volume 68

Number 12

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*Happy Holidays*  
*From The Maryland Pharmacist*

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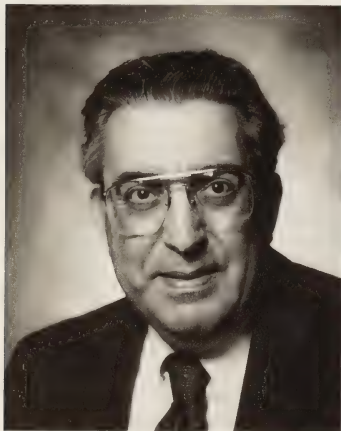
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## President's Commentary

Nicholas C. Lykos, P.D., President



This issue of *The Maryland Pharmacists* is dedicated to the subject of management. Unfortunately, it is a subject we learn more from experience rather than through instruction. Management is an integral part of pharmaceutical care because it insures the financial stability of the practice of pharmacy.

There are many positive aspects of pharmacy's future that bode well for its financial stability. The most important of those aspects is the continued aging of the U.S. population. According to the Census Bureau, the age bracket between 20-39 that comprise of 35% of our population, average 4 prescriptions yearly. The 50 to 69 age group make up 15 percent of our population and average about 9 prescriptions yearly. That population is rapidly growing. Public perception of pharmacy is another positive aspect for our future financial standing. The value of pharmacy is built on trust. For the fourth straight year the Gallop Poll has placed the profession at the top with "high" and "very high" marks for honesty and ethics. Then there is advancing technology. New drugs and product introduction accelerate the use of drug therapies as an alternative to hospitalization. Patients who once would be treated in institutions are now coming to their pharmacists for care. The effective utilization of technology to improve productivity and lower operating costs can broaden operating margins. As the consumers become more health care conscious it benefits the pharmacist to intercede and broaden his or her participation in the health field.

But, of course, even with the positives come the "black clouds." For the community based pharmacist there is ongoing competition with new types of pharmacies -- mass merchandisers with their concept of "one stop shopping," mail order pharmacies well suited for dispensing maintenance medications, combination supermarkets/pharmacies that benefit from frequent shoppers and are accustomed to relatively low gross margins, membership warehouse clubs that generate impressive customer traffic and sales volume, and finally the deep discounter whose operating strategy is extreme low prices and high inventory turnover. Third party and insurance requirements are more complex and detailed as everyone strives to lower health costs. Government regulations, nationally and locally, are complex and ambiguous.

Against and with all these factors, we must strive to use pharmacy management in making headroads and progress. Each practice of pharmacy must develop its management niche -- the close to dozen practices of pharmacy each will continue to develop their own unique theme of management practices and styles.

Each practice must be individualized for your patients and your own ability and desire to manage. What holds true for one practice and one pharmacist may not be necessary, appropriate, or even an option for another. Management decisions should be well thought out; after all, as they taught us in physics, "for every action there is an equal and opposite reaction."

Today, even with many pharmacy management decisions dictated by third-party edicts and government regulations, there is still plenty of room for pharmacy and pharmacists to be innovative in their management decisions. It's up to you how this affects your practice of pharmacy. ■

# Buying and Selling Your Professional Practice

## *A Guide to Establishing Value, Negotiating Terms, and More*

*Alfred Abramson, P.D., Assistant Professor, UMAB School of Pharmacy*



Your pharmacy is one of your most important assets and the decision to sell it is a critical one. The winds of change may be blowing in your mind. Perhaps the combination of growing older and the desire for more leisure time for new and different activities is causing you to consider retirement. Possibly your health is declining and it would prove beneficial to sell now while you are yet able to work, as opposed to later on. Or, maybe you have become bored, burnt-out or both and eager for a new career. In either case, you have been in business long enough and you think this is the right time to sell.

A surprisingly large number of pharmacists hurry into the sales process without adequate preparation. They reach their decisions directed more by emotion than by intelligence and know-how. As a result, problems that could have been avoided occur at all stages.

Once the conclusion to sell is made you must develop a complete selling plan. You will secure the greatest possible return by considering the following general guidelines. Avoid problems in setting the price, finding prospective buyers, evaluating offers, and closing transactions by getting professional advice. A business broker, an accountant, and a lawyer will enhance the probability that you will receive a most lucrative and secure agreement. Be sure to select a business broker who is familiar with selling pharmacies and a lawyer that specializes in selling businesses and real estate if any is involved. Get references on the professionals you

retain.

### **Be Discreet**

The more people other than potential buyers who know your pharmacy is for sale, the less value it will have. This is the opposite to the manner in which residential real estate achieves its value. If your employees learn the business is for sale, you run the risk of losing them, as well as the potential buyers who are interested in retaining a knowledgeable and complete staff. Vendors may request COD payments and customers become worried about services, prices, and the availability of products under new ownership. The net result will be a weakening of your pharmacy's sales and reputation. Confidentiality is essential to avoid damaging consequences.

Check the marketplace and find out if there have been any sales of pharmacies in your area over the past three years. Your drug suppliers and local state boards are excellent sources for this information. Find out if banks are lending money at favorable interest rates? Check to see if the current economic condition has affected pharmacy sales. You will be surprised to find out that pharmacies are still selling and that there is someone out there ready, willing and able to buy your business.

As for preparation, make certain your financial statements and other records are in proper order, so that you never present an inaccurate statement. Documents signed by you and your accountant should provide a reliable picture of your business.

**"We** rely on BBDC in many areas of managing our business in addition to fast and accurate delivery. Merchandising, advertising and special pricing programs help us keep a competitive edge in a highly competitive market..."

—Norman F. Beyer

The future of pharmacy is developing at Bergen Brunswig today. We're one of the nation's leading distributors of pharmaceuticals and other products sold in pharmacies. It's our business to design support systems and marketing and merchandising programs for today's independent pharmacists...as well as for the pharmacists of tomorrow. Always on the leading edge, Bergen Brunswig is working now to meet your future needs.



*Norman F. Beyer, of Butler Pharmacy in Point Pleasant, New Jersey with his daughters, Leslie B. Bugg and Tracye B. Steel.*



**Bergen Brunswig Drug Company**

*Rick Oyler, Division Manager; Jackie Jutchess, Sales Manager  
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### Setting the Asking Price

What is a fair asking price? Setting a fair price can be the key to selling your pharmacy. A knowledgeable broker or appraiser can assist you to determine a price that maximizes your return while facilitating the sale of your business.

The agreed-upon selling price constitutes a meeting of the minds between the seller and the buyer regarding the value of tangible assets established through an appraisal, plus an estimated value for intangibles and goodwill. Since you and the buyer evaluate the business from vastly different viewpoints, agreeing on these values can be fraught with conflict. At some point during the process put yourself in the buyer's shoes to determine the salability of your pharmacy.

You have invested considerable time and money in your pharmacy and are entitled to be appropriately compensated. Through an appraisal, the value of the inventory, fixtures and equipment is determined. The pricing of these tangible assets should be based on current market value. Buyer and seller usually agree on this amount.

The amount for intangibles and goodwill often causes controversy. According to you, the location, lease, customer lists, sales and inventory records, connections with suppliers, special franchise or restricted lines, all contribute to the earning power of the business. Therefore you feel the buyer should be obligated to pay for them.

### Estimating Goodwill

Goodwill can be thought of as the difference between an established, successful business and one that has yet to establish itself. From the buyer's viewpoint goodwill is related to the earning power and potential of the business.

Don't fall into the trap of associating the goodwill price to past investments of time and money. Establish the price based on the actual condition and earning power of the business. If you used your past efforts and capital effectively, the current worth of the pharmacy will be high. The prospective buyer can not be expected to pay for your efforts or mistakes, only the potential earning power. Remember earning power is the key factor.

The prospective buyer is likely willing to pay for good will, but not so much that the final price is so high that the business can only support a salary.

Buyers consider a business for its ability to earn a fair return on investment after deducting a reasonable salary. They are only concerned with the present earnings and future potential of the business. A buyer will willingly pay more than the price of the tangible assets, only if the earning power of the business is greater than that of an outside investment. No one will buy the tangible assets - even at bargain prices - if the business is not producing a sufficient profit.

### The Appraisal Process

The first step to determining an asking price is to get an objective third party evaluation of your business' strengths and weaknesses.

In order to effectively complete a projection of your pharmacy's future earnings, an appraiser will need financial statements and records for at least 3 years. The financial statements must accurately reflect all transactions. The owner can not expect to be compensated for transactions which are not reflected in the official financial statements or tax returns.

In addition he/or she will require that you discuss the following as best you can.

Describe: the current pharmacy industry overall, your pharmacy within that environment, how you envision the future of your business, the factors you consider critical to the future of your business, your competitors, geographic boundaries of your trading area, your advertising and promotions, services (delivery, charge accounts, etc.).

The appraiser will investigate more information than that which you provide, but your assistance facilitates the process. The appraiser or broker will verify your financial statements. If something appears to be incorrect or misleading on your financial statements, it should be recasted (reissued) with clearer wording or more representative dollar figures. For example, recasting may consist of recalculating the value of undervalued assets. The owner's direct and indirect compensation may be added to the net income amount.

Once the figures have been confirmed, they should be compared to those of similar pharmacies. The Lilly Digest is one of the most reliable sources for this comparison. Your pharmacy may deviate from national averages for similar pharmacies, in one or more areas. If so consider the reasons. Identify and rectify problems before placing your pharmacy for sale. Your appraiser or broker will be able to spot problem areas which should be addressed and can be turned around with proper management, thus enhancing the bottom line (net profit). After these changes have been implemented, the financial statements should be recasted to arrive at an appropriate asking price. The new statement must be identified as a "recasted" statement.

Other information to be considered includes: trends in the income stream, the neighborhood of the pharmacy, capacity for physical expansion, room for improvement in management, and changes in demographics.

### Pricing Formulas

There is no definitive equation for pricing and establishing the value of a pharmacy. Different professionals provide several different explanations -- all of which have merit. The span from the informal rule of thumb methods to the techniques of professional appraisers using mathematical calculations.

In doing an exact appraisal approach, financial records and a calculation of assets provide a good foundation for an evaluation. There

are many other factors which may affect the numbers, but will not be taken into consideration here.

An actual appraisal is much more complex and sophisticated than the example presented below. However, this example will give you a clearer understanding of the process for establishing value. Refer to the balance sheet and income and expense statements for Beewell's Pharmacy as each of the appraisal

methods are explained.

### Capitalization Approach

Most prospective buyers would like to get at least a 25% return on their investment. Total income, before taxes, is divided by 25% or multiplied by 4 to show what the buyer would pay in order to get a 25% return.

## Beewells Pharmacy

### Income and Expense Statement For Year Ended December 31, 1991

#### SALES

Prescription	\$ 685,000	82.0%
Other	\$ 150,000	18.0%
Total	<u>\$ 835,000</u>	100.0%
Cost of Goods Sold	560,000	67.1%
Gross Margin	\$ 275,000	32.9%

#### EXPENSES

Proprietor's Salary	\$ 64,050	7.7%
Employee Salaries	\$ 49,075	5.9%
Rent	\$ 30,000	3.6%
Utilities	\$ 9,125	1.1%
Accounting/Legal	\$ 10,600	1.3%
Taxes/Licenses	\$ 15,960	1.9%
Insurance <sup>1</sup>	\$ 5,570	0.7%
Interest Paid	\$ 2,800	0.3%
Computer	\$ 9,600	1.1%
Depreciation <sup>1</sup>	\$ 14,650	1.8%
Miscellaneous	\$ 23,870	2.9%
Total Expenses	<u>\$235,300</u>	28.2%
Net Profit (before taxes)	\$ 39,700	4.8%
Add Proprietor's Withdrawals	+ \$ 64,050	7.7%
Total Income before taxes	\$103,750	12.5%

<sup>1</sup> Not including insurance or depreciation of buildings.

## Beewells Pharmacy

Balance Sheet  
For Year Ended December 31, 1991

### ASSETS

<i>Current Assets</i>	\$ 685,000
Cash	\$ 150,000
Accounts Receivable	\$ 40,489
Inventory	<u>\$ 81,587</u>
Total Current Assets	\$ 179,899

### *Fixed Assets*

Fixtures and equipment and leasehold improvements (net after reserve for depreciation)	\$ 30,062
--	-----------

### *Other Assets*

Prepaid expenses, deposits, etc.	<u>\$ 9,613</u>
----------------------------------	-----------------

<b>Total Assets</b>	<b>\$219,574</b>
---------------------	------------------

### LIABILITIES

#### *Current & Accrued*

Accounts Payable	\$ 30,756
Notes Payable (within 1 year)	\$ 4,960
Accrued Expenses	\$ 6,189
Total Current/Accrued Liabilities	<u>\$ 41,905</u>

#### *Long Term Liabilities*

Notes Payable	<u>\$ 9,360</u>
<b>Total Liabilities</b>	<b>\$ 51,265</b>

<b>Net Worth</b>	<b>\$168,309</b>
------------------	------------------

<b>Total Liabilities + Net Worth</b>	<b>\$219,574</b>
--------------------------------------	------------------

\$ 64,050 Proprietor's withdrawal  
39,700 Net Profit (before taxes)  
\$103,750 Total Income (before taxes)

$\$103,750 \times 4 = \$415,000$  value

$\$103,750/25\% = \$415,000$  value

### Income Approach

At this point, the appraiser would look at the trends in the income stream. If the pharmacy were showing a substantial increase in sales every year, a figure of 2.5 to 3 would be the multiple of the recasted net income. If the pharmacy had substantial decreases in sales his multiple could be 1 to 1.5. We are assuming that this pharmacy has an

average increase in sales and we will use a factor of 2.

The formula used in assessing value for the Income Approach Calculation is: Recasted Net Income x Multiple + inventory.

Interest paid and depreciation are both non-operating expenses and should be added to the proprietor's withdrawal and net profit to get a more realistic interpretation of the recasted net income. Then inventory is added to this figure to derive an asking price.

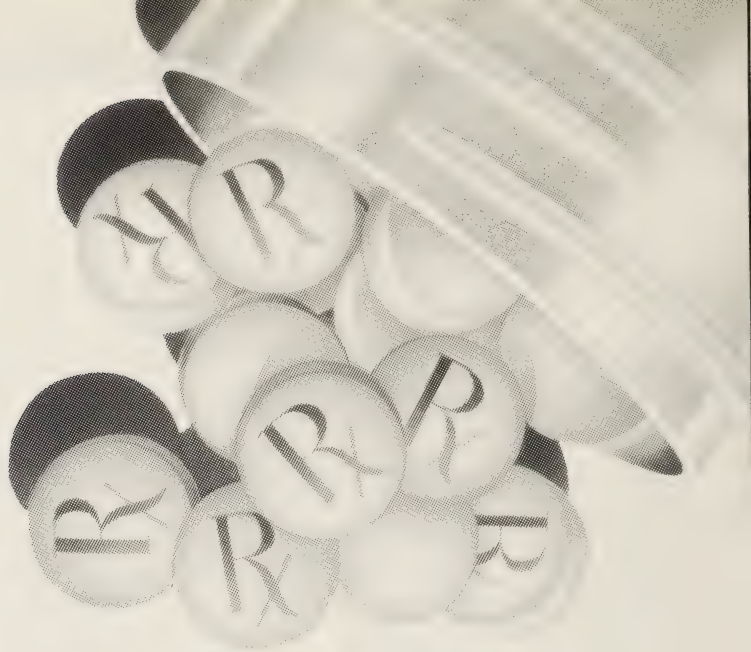
\$ 64,050	Proprietor's withdrawal
2,800	Interest Paid
14,650	Depreciation
<u>39,700</u>	Net Profit (before taxes)
\$121,200	Recasted Net Income

$\$121,200 \times 2 = \$242,400$   
+ \$81,587 inventory = \$323,987 value

### Abstract of Pertinent Factors

From the balance sheet a figure is given for the net worth and added to a value for goodwill. Net worth is calculated by subtracting total liabilities from total assets. Goodwill is generally equal to one year's recasting of net income. The goodwill factor may be a multiple of 1 to 3 of the recasted net income by relating it directly to the increases and decreases in sales volume each year. A pharmacy with sales increases each year would, therefore, have a higher goodwill factor.

\$168,309	Net Worth
<u>\$121,200</u>	Good Will
\$289,509	



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### *Average of All Equations*

Using these three different value calculation methods gives us three prices that range from \$289,509 to \$415,000. Each of these approaches to appraise this pharmacy's value are based on definite facts and figures.

To get a closer approximation of an appropriate pharmacy selling price, add the three factors together and divide them by three.

\$ 323,987 Net Income Approach  
\$ 415,000 Capitalization Approach  
\$ 289,509 Abstract of Factors  
\$1,028,496

$$\$1,028,496/3 = \$342,832$$

With the help of an accountant, appraiser or business broker, who should know the market, you can establish a reasonable value on any pharmacy.

Above all, *the listing price must be an honest and realistic one.*

### **Fair Market Value**

Current fair market value for the business is that price at which a willing seller would sell and a willing buyer would buy neither of them being under any compulsion to sell or buy.

Based on all the information obtained, tax returns and profit and loss statements, our appraisal of Beewells Pharmacy is \$342,000. This price includes all of the assets and an inventory of approximately \$82,000. The purchase price should be adjusted if the inventory is more or less than \$82,000.

Finally the actual price to be paid for a pharmacy practice will often differ considerably from its value as defined here if there are special terms available as part of the transaction. For example, it is worth paying a much higher price than indicated if a very low interest rate is available and the owner will carry a lot of "paper," etc. As a rule, a little work and help from a qualified certified public accountant will help to place a value on the benefits of such special terms. Then a correlation between the value as indicated by this method and the value of the special terms can be established, and appropriate adjustments made.

The current value of a pharmacy is based on past and projected performance. The potential buyer is interested in what financial rewards can be received from owning his or her own pharmacy.

Expect that potential purchasers will scrutinize earning figures. Validity of financial statements must be beyond reproach. Prospective buyers will look at the trends in the income stream. Growth potential of more than the inflation rate is required to lure buyers. Projected growth of 30% per year or more without a history of this growth pattern is difficult for potential buyers to believe. Future growth of 10 to 15% usually seems believable -- providing there is evidence to support the projected pattern.

A professional broker can be invaluable in structuring the deal, because at this point, effective marketing is crucial to closing the deal.

### **Negotiating Terms of Sale**

Negotiating the terms of sale requires the assistance of knowledgeable professionals. You will benefit from having a broker qualifying prospective buyers before you begin negotiations. You do not want to consider a prospective buyer that can not afford to buy your pharmacy. Also, the buyer must be the type of individual that feels he or she can improve the business.

Issues a broker should review for you in advance include the ability to obtain the down payment, the willingness to sign personally for owner financing and what collateral is available.

While your decision is the final one, sensitive issues are better handled by professionals with your instructions. Let your broker or attorney ask the tough questions and deliver any bad news. This will facilitate a friendly relationship between you and the buyer.

Typically an interested buyer will submit a letter of intent to buy your pharmacy. This will include an offer under specific terms and conditions as well as a deposit. If you accept the letter of intent, the buyer's lawyer writes the formal contract for sale. You and your attorney should negotiate the terms of the contract to assure that the final document is clear and defensible in a court of law. You must be fully protected. If there is any owner financing, your attorney should also prepare the note.

### Details Needed to Close

You should have a complete list of what has to be done at settlement. You should even be aware of what the buyer needs to do before you both go to closing.

You will need a copy of the deed if property is included in the sale.

A resolution is needed to sell if your pharmacy is a corporation.

A final inventory figure is a must. Typically, the final inventory is determined after the close of business the day before the settlement by an objective third party. The cost of completing the inventory taking is usually shared by the buyer and the seller.

Essential to the sale is the transfer of banking arrangements, utilities, telephone service, taxes, a breakdown of funds to be disbursed and the clearance of any outstanding liens and accounts receivables and payables, etc.

Business licenses and permits, especially pharmacy licenses and CDS permits, should be applied for early. The buyer should also be aware that they will need to file for new third-party provider numbers.

### Terms of Sale

There are a number of different ways the purchase can be paid. Corporation sale, asset sale, all cash and installment asset contract are examples. Each of these ways has advantages and disadvantages to you, the seller. The most common is the *Installment Asset Contract*.

## Prepare for Buyer's Questions

Some frequently asked questions to be prepared for are:

1. Why are you selling?
2. How much working capital is needed?
3. If you were to continue in business how would you improve daily operations?
4. What are your major revenue sources? (A major revenue source is a product line or service which accounts for at least 10% of your total revenue)
  - a. How would you increase sales for each major revenue source? How did you do it last time?
  - b. Describe potential new revenue sources. What would you do to develop them?
5. What new products would you recommend adding?
6. Would delivery service increase your business?
7. What is the maximum production potential of this business?
8. Who are your employees? (Give names, job functions, compensation, brief employment history, length of employment with you, key skills, etc.)
9. How much of this potential new business could be handled with your current staff and resources?
10. What positions would you add as business grows?
11. What are your strengths and weaknesses?
12. What are your competition's strengths and weaknesses? How would you take advantage of the weaknesses and offset their strengths?
13. Are there any other improvements that you would recommend?

Installment asset contract is where the buyer purchases all assets and the name of the pharmacy but not the pharmacy's liabilities. The seller retains the corporation. All accounts receivable belong to the seller and the seller is responsible for rectifying all outstanding liabilities before the day of settlement.

In this financing scheme, the buyer pays some money down, takes control of the business, and pays the balance

over a period of time to the seller.

An advantage of this method is usually a cleaner deal because there is little discussion about how much of the selling price should be reserved for any future damages. It is also a faster deal to consummate because there are fewer items to verify. In addition, the seller can ask, and should expect, a premium amount because there is a waiting period before the selling price is paid.

The disadvantages of this method are that the seller remains responsible for any assets not purchased and all outstanding liabilities. There may be transfer and other local taxes that the seller will continue to incur. The seller must also comply with the Bulk Sales Act. Another major concern is that the seller must wait for the money and depend upon the buyer's ability to pay in the future. The seller could have sold the business for far less than realized and the business has been impaired.

### Recommendations

If you think there is little risk that there will be future damages for you to satisfy and the buyer will continue to pay, the Installment Asset Contract is a good way to sell a pharmacy business. Bear in mind that because of tax ramifications, you probably would end the corporation one year after the sale. Therefore, your possible liability is limited to one year.

Your risk in selling a pharmacy can also be reduced if an attorney drafts an agreement that 1) makes the sale irrevocable, 2) stipulates specific collateral behind the buyer's promise to pay, and 3) requires both corporate and personal signatures.

Many pharmacies have been sold throughout the country over the past few years. If you feel the time is right, begin the planning process now.

Dr. Fred Abramson is available to pharmacists interested in selling or buying their own pharmacy practice. He can be reached by calling the UMAB School of Pharmacy at (410) 706-7650. Members can also obtain a sample letter of intent to purchase a pharmacy by calling the MPhA offices at (410) 727-0746 or toll-free in Maryland at (800) 833-7587.

**Coming in the  
January 1993 issue of**

## *The Maryland Pharmacist*

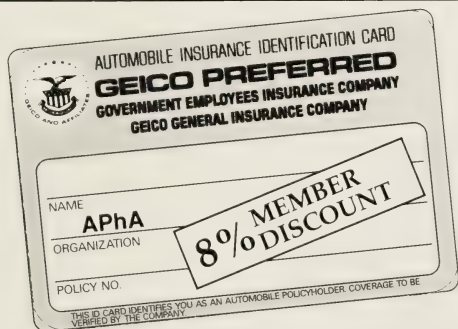
**MPhA's Code of Ethics**

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**The Responsibilities of  
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**A Report from the  
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Consensus Conference**



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# Holiday Hazards

*Lisa Booze, B.S.Pharm., Certified Poison Information Specialist, Maryland Poison Center*



Holidays - a welcomed break in the daily routine - are eagerly and excitedly anticipated each year. The hectic routine and distraction from everyday details, however, create an environment where an accidental poisoning can easily occur. A curious child will explore and taste tempting decorations, lights and plants. Be aware of the most common hazards at holiday time. Know what to do if a poisoning occurs in your home.

Be prepared! The Maryland Poison Center has some recommendations for a safe holiday:

- Keep the poison center's phone number on or next to the phone.
- Use the list below to help poison proof the home at holiday time.
- Call the Maryland Poison Center immediately if you suspect a poisoning. (528-7701 in the Baltimore metropolitan area; (800) 492-2414 elsewhere in Maryland).

**Alcohol** in all its forms - liquor, wine, beer, and perfumes, colognes and aftershaves - can poison or even kill a child. Don't leave gift perfumes under the Christmas tree. After parties are over, empty all beverage glasses before going to bed so that an early-rising child doesn't sample any remains of alcoholic drinks.

**Angel hair** is not poisonous but the finely spun glass may cause cuts or irritation.

**Artificial trees** are made of plastic or aluminum and may cause cuts or choking if swallowed.

**Christmas tree bubble lights** are filled with alcohol or other solvents and could poison a child if the contents of more than one was ingested.

**Candles** are non-poisonous, however, melted wax can cause serious burns.

Most **Christmas tree ornaments** are not poisonous if ingested. Varnish or shellac once dried is not harmful. Antique ornaments may be painted with lead-containing paint. Although they usually do not contain enough to harm a child, it's a good idea to place them high on the tree.

**Icicles and tinsel** are non-poisonous but may be a choking hazard in small children.

**Snow globes** are non-poisonous. The "snow" is usually calcium carbonate and the liquid is water or glycerin.

**Snow sprays** are aerosols. The "snow" is non-toxic but the propellants and solvents can cause poisoning if inhaled or sprayed in the eye.

**Holiday plants** that are put on display or given as gifts are pretty but may be poisonous. Plants such as holly, mistletoe, jerusalem cherry and dumbcane are harmful if eaten. Although the poinsettia has been widely reported as being poisonous, there is little evidence to support this claim. The sap might be irritating but the Maryland Poison Center considers the poinsettia to be virtually non-poisonous. (A poisonous plant list may be obtained from the Maryland Poison Center by calling 328-8122).

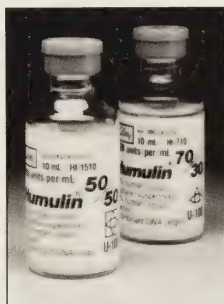
**Christmas tree preservatives** are usually sugar solutions. Homemade preparations such as dilute bleach or aspirin may be dangerous.



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# Mail Order Madness

## How Can Independents Cope?

Anthony P. DeNicola, President, A & D Associates



Independent pharmacists cannot pick up a trade journal or newsletter about our industry without reading one or more articles about mail order pharmacy. The explosive growth and high visibility of this segment of the prescription dispensing environment has created as much controversy as any other issue in the industry over the past three decades. The claims and counter claims by mail order pharmacy operators, independent pharmacists, and the trade associations who represent these groups, have been flying fast and furious in these articles, and in numerous press releases, for a number of years now.

It is becoming more and more difficult for independents to sort out the issues and determine how they can best cope with mail order prescription competition. I believe that independents can survive with and compete against mail order pharmacies in most environments, if they are armed with the necessary education about mail order pharmacy, where it fits in the pharmacy arena, and what its shortcomings are. Once independents capture this knowledge, if they effectively communicate the shortcomings of mail order pharmacy to their customers, they can, in many cases recapture business lost to mail order.

### Types of Mail Order

First and foremost, let's take a look at the mail order pharmacy environment. Are all mail order pharmacies alike? Absolutely not. Just as every independent differs in

character, apothecary versus full line, rural versus urban, large versus small store, so, too, do mail order pharmacies differ significantly. You can rest assured that the newest member of the American Managed Care Pharmacy Association (AMCPA), All Scripts Pharmaceuticals of Vernon Hills, Illinois, has nowhere near the size or scope of the mail order giant, Medco Containment.

Medco's recently released figures reflect total sales of more than \$2 billion dollars on an annualized basis. They claim to dispense more than 25 million prescriptions a year through their mail order pharmacies. Compare this with All Scripts, which is affiliated with Sears Roebuck and their new private pay, direct to the patient, mail order program, and I am sure you would find, if you had access to the figures that they are a very small player in this marketplace. They, along with the fourteen other mail order firms who make up AMCPA, are responsible for almost all the mail order marketshare in this country. Within that environment, independent pharmacists need to know, first and foremost, that there are different types of mail order programs.

Included among these are:

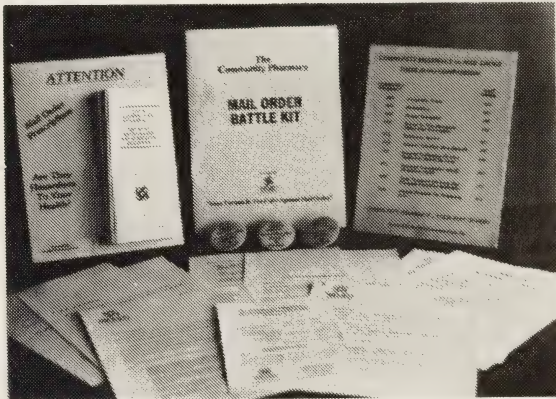
1. *Private pay mail order programs.* The principal one of these is the AARP mail order pharmacies. Patients receive medication by mail and pay cash for their prescriptions. Sometimes they are reimbursed by indemnity insurance programs.
2. *Mandatory third-party mail order programs.* These mail order programs

have been instituted in recent years by a variety of third-party payors, insurance companies, employers, government agencies, and others, who, feeling the need to contain prescription costs, have gone to mandatory mail order for certain segments of their prescription programs.

3. *Optional third-party mail order programs.* Many of the third-party payors, particularly those dealing with the trade union environment, have been reluctant to mandate mail order on their beneficiaries. Accordingly, they offer optional mail order programs, usually combined with significant financial incentives, to get the patient to use mail order. In the final analysis, they do not mandate the use of mail order pharmacy.

### Mail Order Marketshare

What share of the \$40 billion plus prescription drug market does mail order pharmacy actually control? Depending on whose press releases you read and wish to believe, that number varies significantly. The most recent figures released that appear to have a reasonable amount of credibility, captured from a variety of statistical reporting agencies, indicated that mail order pharmacy accounts for slightly less than nine percent of the dollars of prescriptions filled in this country. Since the vast majority of mail order prescriptions are for maintenance drugs, this dollar volume probably represents significantly less than nine percent of the *total number* of prescriptions dispensed. Most mail order prescriptions are for large quantities



**Mail Order Battle Kit**

During the past four years, retail pharmacy has lost 9.5% of prescriptions sales while mail order prescriptions sales have grown by almost 79%. To help combat this trend, ParMed Pharmaceuticals has developed a "Mail Order Battle Kit" containing information and materials needed to effectively communicate to the public the strengths of community pharmacy as a healthcare provider.

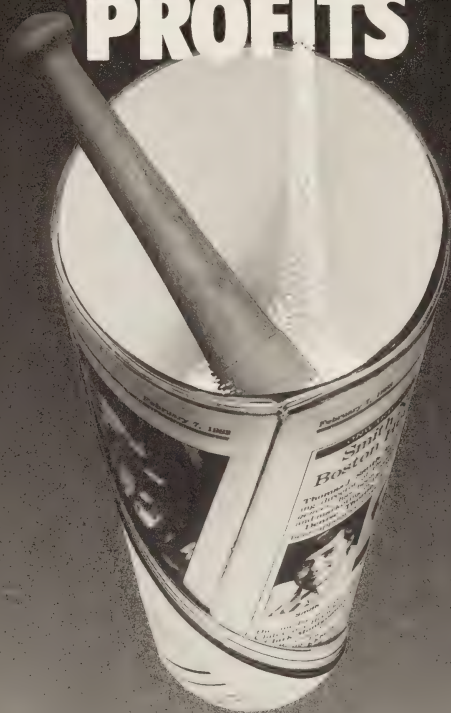
The kit includes two separate counter cards, samples letters to be sent to patients and prescribers, sample press releases, buttons, and more. To order, contact ParMed at (800) 727-6331. The "Mail Order Battle Kit" costs \$19.95.

of maintenance drugs, a 90 day supply or more, more expensive than the average prescription.

Will mail order pharmacy grow this marketshare significantly? There is great debate over that issue. While their trade association would like to lay claim to 15 to 25 percent of the market within a few years, there are serious doubts as to whether they can ever achieve these numbers. From this writer's perspective, the growth of

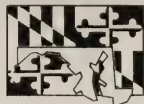
mail order, while explosive in its early days in the middle to late '80's, has now leveled off significantly and appears to be, from reviewing some statistics, more or less flat. This, coupled with some of the bad press that the mail order pharmacy industry has received, by virtue of incidents of inaccurate dispensing, has served to put a crimp in the growth of the mail order segment.

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It's interesting to note that the "experts," former pharmacy benefits managers for large corporations and government like Beech Hall of General Motors and Doug Forrester of the New Jersey State Pension Program, are now saying that mail order pharmacy is not good pharmacy and never saved their respective employers any real money. I think this is an issue that many independent pharmacists have been aware of for many years. Unfortunately, independents don't always have the forum to send this message to the general public, and/or to the benefits managers who make third-party prescription purchasing decisions. One of the things independents need to do is educate customers and benefits managers, whenever possible, about the shortcomings of mail order.

In the independent PSAO environment, there is no doubt that intelligent network managers like John Pike, Patrick Berryman, Lonnie Wilson and others, have developed effective alternatives to mail order, for those purchasers of prescription drugs who are willing to listen to things that make good sense for their beneficiaries and their pocketbooks. These alternatives, while not as price competitive as the mail order option, can, in many cases, provide as much cost savings to employers as dealing with the giant mail order firms who only offer price.

### **Preferential Pricing Advantages**

Are mail order firms receiving preferential pricing from pharmaceutical manufacturers? This fact has been documented by NARD

more than once over the years. In order to receive preferential pricing and special discounts, there is no doubt that mail order firms must deliver something to the pharmaceutical companies, increased sales, increased marketshare, or some other value-added benefits, that would warrant a price decrease. Where the real problem comes about is when these lower prices are provided to small mail order firms who do not provide any of the aforementioned benefits. This writer has serious doubts about many mail order pharmacies ability to provide the benefits they are "selling" to the PMA companies. Nonetheless, in some cases, the sale has been made and there are documented cases of lower prices available to mail order firms on single source drugs. This has led independents to try to find ways to present this same posture to the manufacturers.

While I respect and understand independents' desire to level the playing field, and obtain the best prices possible, I strongly caution any independent, particularly those in PSAO's, about the possibility of "getting into the mail order business," a term I have heard at many meetings around the country in recent years. Let's face it, as practicing pharmacists, we know that mail order pharmacy is simply bad pharmacy. The lack of personal contact, face-to-face counseling, drug regimen monitoring, and all the other services routinely performed by independent pharmacists makes mail order pharmacy a very unattractive alternative to community-based dispensing.

I believe that independents need to fight mail order by communicating with patients and with third-party payors about the negatives of mail order and the positives of community-based service. At the same time, we need to sharpen our pencils and learn how to do business in the maintenance drug environment with the shortest margins possible, to keep that share of the market in the independent store. There are many aggressive and innovative independents around the country who have found ways to cope with and co-exist with mail order pharmacy programs, third party as well as private pay. The challenge to independents is to know what's out there in the way of mail order programs, to know what their customers needs and wants are, and to meet those needs and wants effectively.

If we can do that, and continue to communicate our message to all the people involved in the healthcare community, beneficiaries as well as providers, about the negatives of mail order pharmacy, I believe that independents can certainly co-exist with mail order pharmacy programs. We must remember, mail order pharmacy will never go away. It is a \$3 billion plus industry at this point in time. What independents need to do is try to contain it as best they can, by offering viable alternatives and by constantly communicating with customers, third-party payors, and other healthcare providers. ■

# Drug Information Questions

## *Psychiatric Uses of Nonpsychiatric Drugs*

Jami S. Lingle, R.Ph., Babette S. Prince, Pharm.D., UMAB Drug Information Center  
*This article provided under a grant-in-aid from **Glaxo***

### *Drug Information Request*

Why are some of the nonpsychiatric drugs used for psychiatric purposes? What are some of examples?

### *Response*

As pharmacists, often the only piece of information we receive about a patient is their medication profile. We try to provide service not only by filling and dispensing the appropriate medication, but also by reviewing the medication order for appropriateness, efficacy, potential adverse effects and drug interactions. Using our clinical skills, we attempt to address issues which may affect patient compliance and therapeutic outcome from drug therapy.

Although psychiatric patients are likely to have general medical problems like everyone else, sometimes their medication profiles can be misleading. Many drugs which are approved for non-psychiatric indications are routinely used in psychiatric patients for treatment of primary psychiatric indications. This practice has developed gradually over time, from the observation that certain drugs used for systemic indications quite often have central nervous system effects. Clinicians have attempted to harvest the adverse effects of certain systemic medications as primary treatment for psychiatric illness.

Psychiatric patients are very likely to be noncompliant with their medications. Noncompliance is also a leading reason for exacerbation of psychiatric disease and readmission to the hospital. Pharmacists can improve compliance by underscoring the importance of proper drug use and by alerting patients to potential adverse effects. To provide better service to this group of patients, it is important to have an understanding of the psychiatric use of these agents and for pharmacists to be available and unafraid to answer questions.

### *General Therapeutics in Psychiatric Patients*

Within a diagnostic class of mental illness, there is usually an accepted first line of psychiatric agents which have been shown to be efficacious. When first line options are ineffective, clinicians look to alternative

therapies. Sometimes these are second line psychiatric drugs, and other times clinicians employ medications which are not traditionally indicated for psychiatric illness. Generally, clinicians attempt to treat a patient with as few medications as possible, with single agent therapy being preferred over multi-drug regimens. However, several medications may be needed to adequately treat the patient. In some patients, the augmentation of one drug in combination with another drug is more effective than either single agent given alone. Patients may undergo several therapeutic trials before a clinician finds the best drug therapy.

### *Clinical Trials in Psychiatric Patients*

Clinical drug trials in psychiatric patients are often difficult to interpret. A psychiatric illness is rarely a single entity, and often there is no clear etiology or pathophysiology. Although we attempt to label people with a diagnosis, quite often patients with the same diagnosis may have very different symptoms. Not all patients are responsive to drug therapy, and each patient must be evaluated and treated individually.

A substantial proportion of psychiatric drug literature consists of case reports and small group studies. Large clinical trials in psychiatry are difficult to conduct for several reasons. Patient populations are often not homogenous in behavior and pathology, despite similar diagnosis. Assessment in clinical trials is often subjective, and may vary from clinician to clinician. Patients tend to be on several medications and therapies concurrent with study protocols which may confound results. Often the clinical outcome criteria is unclear or unstated, left open to interpretation by the researchers. Also, it is the nature of psychiatric illness to wax and wane, making it less clear that drug effects are completely responsible for clinical improvement.

These factors are the reasons that there are few well-controlled, double-blind, large-scale studies from which we can derive therapeutic information. Instead, we base our clinical decisions on literature which is comprised of controlled studies with small numbers of patients, unblinded studies, uncontrolled trials, and case reports.

This does not mean there is a lack of rational approach to innovative drug therapy in psychiatric patients; rather, some of the doctrines by which we judge general medicine studies may not apply to psychiatric studies.

### Nonpsychiatric Drug Therapy

The major classes of nonpsychiatric drugs used in psychiatry fall into the following categories: anticonvulsants, cardiac drugs, hormonal therapy, and stimulants. There are also some miscellaneous agents, such as antihistamines and antiparkinson drugs which are also widely used. The following is a brief review of clinical literature suggesting potential usefulness for some of these agents. It should be emphasized that these medications are not FDA labelled for these indications, and all patients may not respond to these suggested therapies. Rather, these are potential alternatives when there is no traditional therapy or traditional therapy is ineffective.

#### Anticonvulsants

Anticonvulsants were introduced into psychiatry through the observation that emotional disorders in epileptic patients were often lessened upon medical management of seizure activity. Of all the classes of nonpsychiatric drugs, this perhaps is the most common group studied and prescribed for psychiatric indications.

Primarily, these agents are effective in treating seizures by interfering with membrane potential and conductivity of neuronal cells. However, this anti-seizure pharmacology may not explain the mechanism by which these agents are applicable in psychiatric indications.

**Carbamazepine.** Carbamazepine has been extensively studied in the treatment of bipolar disorder, both as a single agent and in combination with lithium.<sup>1-4</sup> Carbamazepine has acute antimanic and antidepressant effects, and offers prophylactic treatment comparable to lithium in some bipolar patients.<sup>3</sup> Certain subgroups of patients tend to respond better to carbamazepine therapy: rapid cyclers, patients with severe mania, and patients with mania that is associated with a sad affect.<sup>1,5</sup> In patients with only depressive symptoms, carbamazepine

does not appear to be effective.<sup>6</sup>

There is a substantial amount of literature to support the use of carbamazepine in aggressive behavior, both in psychotic and nonpsychotic patients.<sup>7-10</sup> Although there are contradictory reports in the literature related to efficacy, carbamazepine may have a limited role as an augmenting agent to reduce aggressive behavior in schizophrenia.<sup>11</sup> There has been no conclusive evidence to show carbamazepine reduces core psychotic symptoms.<sup>12,13</sup> Carbamazepine is generally not effective in treating eating disorders, but there are some reports of improvement in symptoms in bulimic affective disorder patients.<sup>14</sup>

**Valproic Acid.** In refractory bipolar patients, valproic acid may be useful either alone or in combination with lithium and/or carbamazepine. Valproic acid also has a potential role in the treatment of patients for whom carbamazepine or lithium therapy is contraindicated.<sup>2,3</sup> Valproic acid has shown some usefulness in the treatment of acute mania, mixed states, and in prophylactic therapy.<sup>15-17</sup> Valproic acid may be most beneficial in therapy of treatment resistant, rapid-cycling bipolar patients<sup>18</sup> and in patients with neurologic abnormalities or organic brain syndrome.<sup>15</sup> In patients with only depressive symptoms, valproic acid has not been shown to be useful.<sup>6</sup>

**Other anticonvulsants.** Phenytoin has been widely studied for its usefulness in many psychiatric illnesses, such as affective disorders, violent behaviors, psychosis, and sleep disorders.<sup>19,20</sup> Phenytoin may have some usefulness in the treatment of intermittent explosive disorder, and in controlling symptoms of anger, irritability, and anxiety.<sup>21-25</sup> Phenytoin has provided some moderate improvement of symptoms of bulimia in some studies,<sup>26</sup> but other studies have shown phenytoin to be equal to placebo.<sup>27</sup>

There is some evidence that clonazepam may be effective in the treatment of acute mania in combination with lithium.<sup>3,28,29</sup> Clonazepam may also be a useful alternative in the treatment of social phobia<sup>30-32</sup> and panic disorder.<sup>33,34</sup> Trials of clonazepam in the treatment of depression have been contradictory; some reporting success and other failure.<sup>6,35</sup>

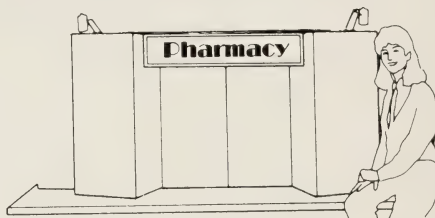
## Cardiac drugs

Cardiac drugs are the second most common group of nonpsychiatric drugs used for psychiatric indications. The rationale behind their use relates to the ability of these agents to affect neurotransmitter systems which are present both peripherally in the cardiovascular system and centrally in the brain. These agents affect transmissions mediated by epinephrine, norepinephrine, and acetylcholine. They also affect the peptides of the renin-angiotensin-aldosterone system, and alter membrane potentials through interactions with sodium, potassium, and calcium ions. All of these neurotransmitters, peptides, and ions are normal components within the brain, and dysregulation of one or more of these systems may contribute to the pathophysiology of certain mental disorders.

**Calcium Channel Blockers.** As a class, the calcium channel blockers are heterogeneous in their specificity for certain tissues, with some having more central effects (e.g. verapamil and nimodipine). Interestingly, many antipsychotic drugs also possess calcium channel blocking ability (e.g. pimozide, thioridazine, tricyclic antidepressants). Most studies with calcium channel blockers in psychiatric patients have used verapamil, however some studies have suggested diltiazem may also be useful.

Verapamil has been studied in single-blind<sup>36</sup> and double-blind<sup>37</sup> trials in patients with affective disorders, with its effects being comparable to lithium. However, an open trial in lithium-resistant patients did not support the use of verapamil in acute manic events. Verapamil should be considered a third line agent for treatment of affective disorders after treatment failures with lithium, carbamazepine, antipsychotics, and valproic acid.<sup>3</sup> The use of verapamil in unipolar depression is not as well studied, and appears to have limited usefulness.<sup>6,38</sup> Also, a double blind, placebo controlled study of the use of verapamil in panic disorder suggests that verapamil may be useful therapy in this area.<sup>39</sup>

Several studies have shown lack of therapeutic efficacy for verapamil in treating the thought disorders of schizophrenia.<sup>40,41</sup> However, in combination with



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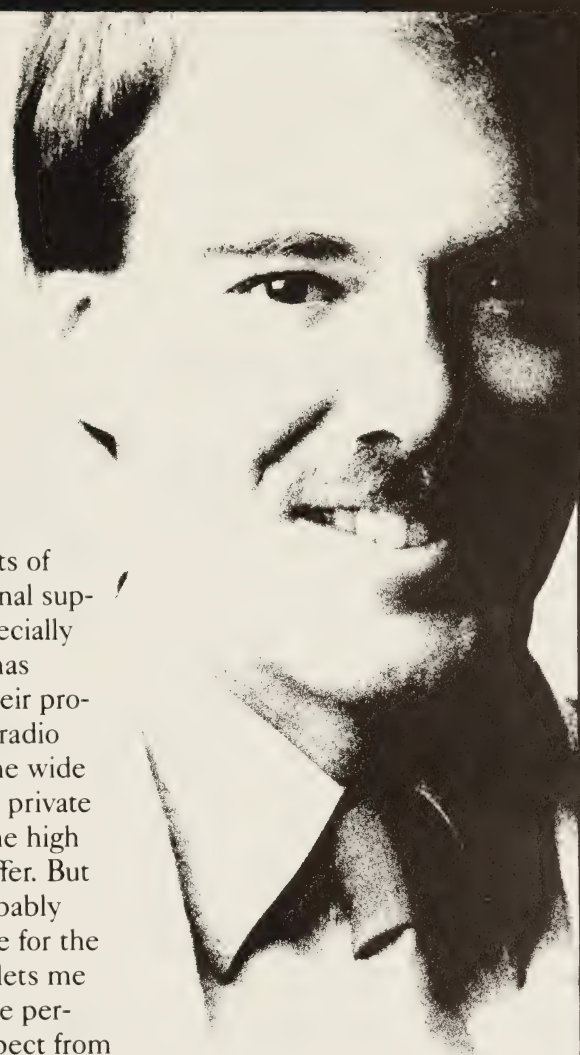
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neuroleptics there may be some usefulness in reducing the negative symptoms of schizophrenia. Diltiazem and verapamil may also be useful as adjuvant therapy in tardive dyskinesia.<sup>38</sup>

**Beta Blockers.** Beta blockers have been well studied in the psychiatric community.<sup>42</sup> Due to the high degree of lipophilicity and ease of penetration into the CNS, propranolol has been the most commonly studied beta-blocker in psychiatric patients.

Beta-blockers appear to be successful for treating somatic components associated with anxiety disorders, although they are not as effective as the benzodiazepines or standard therapy.<sup>43-45</sup> Beta blockers may be particularly useful in patients who have a large physical component to their anxiety. Beta-blockers have also been useful in the treatment of panic disorder, performance anxiety, social phobia and hyperventilation syndrome, but have limited usefulness in agoraphobia, and drug-induced panic reactions.<sup>38</sup>

Beta-blockers may be effective in the treatment of aggression in both patients with organic brain syndromes and with normal physiology. Affective aggression appears to be more responsive to beta-blockade than predatory aggression, and some feel that efficacy may be related to the lipophilicity of the beta-blocker.<sup>38</sup>

There have been mixed results in studies of single agent and augmentation therapy with beta-blockers in patients with schizophrenia.<sup>12</sup> In successful augmentation therapy, researchers propose the antipsychotic effects of beta-blockers may be related either to central beta effects or an increase in blood levels of neuroleptics.<sup>46</sup> Beta-blockers may be efficacious by lessening the akathisia commonly associated with schizophrenia and neuroleptic use.<sup>47,48</sup> Beta blockers may also be useful in decreasing the tremor associated with lithium therapy.<sup>38</sup>

**Clonidine.** Clonidine has been shown to decrease hyperactivity and impulsivity significantly better than placebo in children diagnosed with Attention Deficit Hyperkinetic Disorder (ADHD).<sup>49</sup> Long term efficacy and tolerance to therapeutic effects have not been determined. Clonidine has been shown to be superior to placebo in panic disorders, particularly in short term management of patients with somatic symptoms of

anxiety.<sup>50-54</sup> Clonidine has been useful in some cases of social phobia and obsessive compulsive disorder, but more studies need to be conducted.<sup>38,50</sup> Several open trials have suggested that clonidine may be useful in the short term treatment of mania, particularly in combination with other antimanic drugs.<sup>51,55</sup> However, tolerance develops quickly to the antimanic effects of clonidine, and long term usefulness has not been established. Clonidine may be useful in brief treatment of acute psychosis,<sup>56</sup> although its usefulness in schizophrenia is unclear.<sup>50,57</sup> In case studies, clonidine has been thought to decrease the symptoms of tardive dyskinesia and neuroleptic-induced akathisia.<sup>38</sup>

**ACE Inhibitors.** There are some reports of ACE inhibitors being effective for reducing depression in depressed hypertensive patients.<sup>58</sup> To date, there have been no studies to indicate ACE inhibitors may be used in non-hypertensive depressed patients. However, it may be therapeutically preferable to use these agents to treat depressed, hypertensive patients.<sup>38</sup>

**Reserpine.** Reserpine may be useful in the treatment of mania and schizophrenia psychosis through the depletion of catecholamines, primarily dopamine and norepinephrine.<sup>12</sup> However there are many adverse effects to reserpine, one of which is clinical depression. Because there are safer, more effective drugs, reserpine is usually attempted only in patients refractory to other agents.<sup>12,38</sup>

### Hormonal Therapy

There are many interrelationships between hormonal function and psychiatry. Both hyperthyroid and hypothyroid states may accompany psychiatric symptoms,<sup>59</sup> and some clinicians find usefulness in thyroid hormone supplementation in depressed patients.<sup>60,61</sup> Estrogen supplementation has also been used to augment antidepressant therapy in postmenopausal women, but there have been mixed results reported in the literature.<sup>62</sup>

<sup>64</sup> Monthly menstrual cycles often bring about mood changes, and some clinicians have noted mood stabilization while treating patients receiving oral contraceptives. Also, depot medroxyprogesterone has been found to suppress certain behaviors of male patients who express hypersexuality or inappropriate sexual

behavior.<sup>65,66</sup>

### Stimulants

Stimulants produce their effects through direct neuronal release of dopamine and norepinephrine, as well as blockade of the reuptake of catecholamines. Dextroamphetamine, methylphenidate, and pemoline are the most effective treatment options available to treat both children and adults diagnosed with Attention Deficit Hyperkinetic Disorder (ADHD).<sup>67</sup> Other stimulants, such as caffeine and deanol, have been studied in ADHD but have proven less efficacious.<sup>68,69</sup>

Short term stimulant therapy may be used as a diagnostic tool in depression, where a positive response to several days of stimulant therapy may predict potential success of long term tricyclic antidepressant therapy.<sup>70</sup> Also, in refractory cases, stimulants may be useful to treat the depressive symptoms. Medically ill depressed patients, apathetic and withdrawn geriatric patients, and patients with chronic fatigue may be more likely to respond to stimulant therapy.<sup>51</sup> In several studies, stimulants appear to be more efficacious in treating depression in women than in men.<sup>72,73</sup>

Although it may seem contradictory, stimulants have shown some success in the treatment of eating disorders. Clinical studies have suggested that fenfluramine may be useful in the treatment of bulimia by decreasing frequency of urge to vomit, binge eating, and depression.<sup>74</sup> Also, fenfluramine augmentation with fluoxetine or clomipramine has been useful in decreasing typical symptoms in a small study of obsessive compulsive patients who were unresponsive to traditional therapy.<sup>75</sup> Other stimulants have also had modest success in diminishing some symptoms of obsessive compulsive disorder, but further studies are needed to confirm these results.<sup>70</sup>

### Antiparkinsonian Agents

Anticholinergics such as benztropine and trihexiphenidyl are frequently used to treat drug induced extrapyramidal adverse effects common in patients who have received neuroleptics. Selegiline, which is approved

for early treatment of Parkinson's disease, inhibits monoamine oxidase B found predominately in the brain. Selegiline has been studied as treatment for depression, however it is only useful at high doses<sup>76</sup> where it loses its specificity for MAO B. Therefore, selegiline functions much like the other MAOIs and offers no advantage as an antidepressant. L-dopa has been used in refractory schizophrenic patients with mild success, however its usefulness in psychiatry is questionable and may actually exacerbate schizophrenia.<sup>12</sup>

*Antihistamines.* Hydroxyzine and diphenhydramine have been used for their sedative and calming effects in patients with anxiety.<sup>77</sup> Although they are less effective than benzodiazepines, they have less potential for dependence. Diphenhydramine and doxylamine are also frequently used for their sedative effects to treat sleep disorders. Antihistamines are limited in their usefulness by their anticholinergic effects and potential for tolerance in as little as seven days.<sup>78</sup>

Cyproheptadine is an antihistamine and a serotonergic antagonist which may be useful as an appetite stimulator in anorexia nervosa patients. Although early studies showed no significant difference compared to placebo,<sup>79</sup> later studies with higher doses produced weight gain and improvement in depression.<sup>80,81</sup> A bulimic subgroup of anorexics also showed some improvement with cyproheptadine therapy, evidenced as decreased rate of weight gain. The low occurrence of adverse effects and potential efficacy of this agent suggests further study may be warranted.

### Vitamins

There appears to be limited support for the use of niacin, vitamin B<sub>6</sub> and mega-doses of multivitamins for treatment of patients with psychiatric symptoms. The only exception to this may be autistic children, some of whom appear to benefit from high dose therapies of vitamin B<sub>6</sub> and magnesium.<sup>82</sup>

### Miscellaneous Drugs

Metoclopramide has been used as an adjunct in anorexia therapy to increase gastric emptying time and decrease bloating, abdominal distention and pain which may be associated with feeding anorexic patients.<sup>83</sup> High dose naltrexone (200-300 mg) may be efficacious in the treatment of bulimia, but low dose therapy has been shown not to be effective.<sup>84,85</sup>

### Conclusions

As briefly outlined above, there are many somatic medications which are used to treat psychiatric illnesses. As pharmacists, we can better assist our psychiatric patients by having an appreciation of the complexity and potential duality of their medication regimens. Caution should be taken not to assume an indication for a specific medication, but advice on adverse effects and drug interactions will remain the same. The dosages of these medications may or may not correlate with the traditional therapeutic doses, so a careful eye must be directed towards detecting toxic effects. As psychiatric patients have a high incidence of noncompliance, pharmacists can have a significant effect by simplifying dosage schedules, clarifying instructions, and educating the patient whenever appropriate. Each psychiatric patient has individual needs which need to be assessed with each new prescription, and understanding the principles behind drug selection better prepare the pharmacist to serve his psychiatric patients.

### References

A full copy of the references used in this article are available to all readers by calling *The Maryland Pharmacist* editorial offices at (410) 727-0746 or toll-free in Maryland at (800) 833-7587.

## On the Corner

Frank McGinity, P.D.

According to Maryland law, prescribers must write prescriptions legibly *and* must have an identifiable signature. I thought you'd enjoy deciphering this prescription I recently received. The answer to this month's prescription will appear in next month's *The Maryland Pharmacist*.

This one is actually pretty easy to guess -- if you can by using either the strength or the drug name.

In the meantime, while you're figuring this one out, send or FAX your unusual prescriptions to "On the Corner," MPhA, 650 West Lombard Street, Baltimore, MD 21201, FAX (410) 727-2253.

*Chlorzephate 7.5*  
*30*  
*5 fl 5 10*

### Last Month's Answer:

Coumadin 12.5mg, #30, 1/2 tab q morning  
(I did have to call the doctor to have it changed)

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YOU NEED  
THE BEST  
INSURANCE  
ADVICE...

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## \$700,000 Settlement for Dispensing Lindane

David B. Brushwood, J.D.



The United States District Court for the District of Massachusetts has recently ruled on a preliminary motion in a case brought by a patient against the manufacturer of generic lindane lotion. What is important to pharmacists is that the motion itself was necessitated by the settlement of a companion case brought against the pharmacy where the lindane lotion was dispensed.

In November, 1986, the plaintiff's 14-month-old son was diagnosed as having scabies, for which his doctor prescribed Kwell lotion. The pharmacist filled the prescription with a generic version of lindane lotion. The lotion was used numerous times during November and early December, 1986.

The child was subsequently diagnosed as having permanent neurological damage, including serious developmental delays, a seizure disorder, and cerebral palsy. Experts retained by the plaintiff were of the belief that the child's injuries were the result of using the lindane lotion.

The mother sued the manufacturer and the pharmacy on behalf of her son. Her allegations against the pharmacy was that the pharmacist had negligently failed to provide adequate dispensing information to her. On January 28, 1992, the plaintiff settled this claim against the pharmacy for \$700,000. The case continues with the manufacturer.

There are two important messages in this case. First, pharmacists have a duty to warn patients about potential adverse drug effects. Although the court did not specifically hold that this duty exists, it didn't have to. The payment of a large settlement speaks for itself. Second, when dispensing generic drugs, pharmacists should be certain that they are dispensing whatever patient-directed information they would include with the trade name drug.

A seemingly innocuous drug such as lindane lotion can be harmful if misused. Many other drugs have similarly serious adverse effects that can be controlled if adequate information is provided. The law requires that pharmacists meet the responsibility to provide adequate information under such circumstances. ■

Based on: *Santiago v. Barre National, Inc.*, 1992 Westlaw 134183 (D.Mass. 1992)

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# Dickinson's Pharmacy

*Jim Dickinson*

*An invitation.* Like other busy people, I'm not much of a "joiner." I feel guilty about that sometimes, but in this high-stress world, you have to set priorities for yourself or you'll go to pieces.

So I'll understand if you elect to pass up this invitation from me. It's an invitation to be in my confidential Register of Non-Participating Pharmacists. Without charge.

Its sole purpose is to preserve pluralism in health care (patient freedom of choice). It will do this by essentially doing nothing -- just standing in reserve, just in case (heaven forbid!) it should be needed.

That need would arise if, at some future time, a third-party administrator or other entity should decide to force its prescription plan beneficiaries to use only a "participating pharmacy."

In other words, if a plan refused to directly reimburse a beneficiary for his/her covered pharmacy expenses after he or she has paid them, I would get in touch with pharmacies on my confidential Register of Non-Participating Pharmacies to see how many wanted to protest in some way.

Perhaps there would be enough interest to support a test case in court that might, if successful, establish the legal principle that health programs may not refuse coverage to a beneficiary who is unable for any reason to patronize only a "participating pharmacy."

As health programs are narrowing the range of choices available to covered beneficiaries -- eg. by restricting them to close panels of pharmacies -- the spirit of competition in the pharmacy marketplace is being extinguished.

Taken to its logical conclusion, this trend would leave both the provider and the patient powerless. The choice of pharmacy, prescriber, and even drug of choice, would be left to a secret and unaccountable bidding process between remote corporations.

It hasn't happened yet, that I know of, but the day of onset is clearly visible, rushing to meet us -- the winning bidder will have its detailed formulary in place, its peer review and DUR panels set up, its capitated pricing locked tight, its suppliers identified and bound, and its participating pharmacies exclusively committed.

---

*Have you arranged  
alternate payment plans for  
patients whose third-party  
won't reimburse you  
enough.... or at all?*

*If so, you'll want to sign up  
for Dickinson's register.*

---

Millions would be disenfranchised of their natural right to pick and choose. In the process, their right to sue for recovery of losses related to care received would be emasculated in a maze of potentially culpable, hard-to-identify, shared decision makers.

As I said, I think it hasn't happened yet. But one of the important steps along the road to that scenario would be the decision of a major plan to require its beneficiaries to get all their prescriptions filled

only at X's Drug Stores, Inc., or Y Mail-Order, Inc.

That precedent will be established when a plan decides that it will no longer reimburse a beneficiary *anything* (whether 50% of actual charge, AWP minus X%, or formulary price less X%, or whatever) if they get a prescription filled at a non-participating pharmacy.

At that time, if the decision affects enough people, the pharmacists on my confidential Register of Non-Participating Pharmacies might elect to take a stand and test the decision.

Or they might not. At least they would have a choice, and the burden of deciding would not fall on just one individual, or a few.

You might wonder if such a confidential register would be better maintained by one of the official bodies in pharmacy. I thought about that, too, and decided that they might worry about legal constraints (non-profit entities are not as free as individuals in the eyes of the law).

If some official body wanted to do this, I would poll the pharmacists in my register to see if they preferred to transfer.

Does your pharmacy qualify for admission to the register? It need not refuse all third-party plans (but it may). As long as you have elected not to participate in any plan because of its unfavorable terms, but you continue to fill prescriptions for one of its beneficiaries who is in turn reimbursed directly by that plan, you qualify.

*Concluded on page 31....*

This month's questions are taken from the articles in this issue. Circle your answers to the following questions and mail the entire page with \$5.00 payment (\$10 for non-MPhA members), to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. The completed quiz for this issue must be received by May 31, 1993. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name \_\_\_\_\_

Social Security Number \_\_\_\_\_

Address \_\_\_\_\_

City/State/ZIP Code \_\_\_\_\_

Is this program used to meet your mandatory CE requirements? ☐ Yes ☐ No  
 Was this issue/article useful to you in your practice? ☐ Yes ☐ No

1. Which of the following professionals' services are appropriate in the selling or purchase of a practice:

- a. An attorney
- b. An accountant
- c. A professional broker or appraiser
- d. All of the above

**For the four following questions, use these financial figures for a fictitious Maryland pharmacy.**

Total Income Before Taxes	\$300,000
Recasted Net Income	\$360,000
Net Worth	\$200,000
Inventory	\$100,000
Good Will Factor	1.5
Recasted Net Income Factor	2

2. Using the Capitalization Approach, what is the value of this pharmacy?

- a. \$ 120,000
- b. \$ 75,000
- c. \$ 1.2 million
- d. \$ 300,000

3. Using the Income Approach, what is the value of this pharmacy?

- a. \$ 820,000
- b. \$ 700,000
- c. \$ 720,000
- d. \$ 640,000

4. Using the Abstract of Pertinent Factors Approach, what is the value of this pharmacy?

- a. \$ 650,000
- b. \$ 740,000
- c. \$ 720,000
- d. \$ 1.2 million

5. What is the "Average of all Equations" value for this pharmacy?

- a. \$ 850,000
- b. \$ 820,000
- c. \$ 1 million
- d. \$ 920,000

6. As soon as you have decided to put a pharmacy practice up for sale, which should you do?

- a. Tell your employees about the sale
- b. Advertise in *The Maryland Pharmacist*
- c. Get financial records together
- d. Call your wholesalers for assistance

7. In an Installment Asset Contract, the:

- a. Buyer purchases assets and liabilities
- b. Buyer purchases assets only
- c. Seller retains inventory and assets
- d. Seller retains assets except inventory

8. The cost of a final inventory should be:

- a. Paid by the buyer
- b. Paid by the seller
- c. Paid equally by the buyer and seller
- d. Subtracted from the pharmacy's net worth

9. In determining Recasted Net Income, add the proprietor's salary/withdrawals, interest paid, net profit, and:

- a. Inventory
- b. Accounts Receivable
- c. Depreciation
- d. Accounts Payable

## Dickinson's Pharmacy

*Continued from page 29...*

To register, send your name, address, phone number and the name(s) of any plan in which you do not participate for direct pharmacy reimbursement but whose beneficiaries you continue to serve by an alternate payment arrangement.

Plan identification is vital (and the reason for the register's confidentiality) because how else would I know whether to poll the registrants about taking action?

In the hypothetical event that such a poll could be triggered, it would most likely come from a call or letter asking, "Did you know that Plan X is refusing to reimburse patients for covered prescriptions filled in a non-participating pharmacy?"

Since Plan X might not readily admit this, I would have to consult other pharmacies who had Plan X beneficiaries, in order to confirm.

To register, send the requested information to me at Post Office Box 848, Morgantown, WV 26507-0848.

This feature is presented on a grant from *Dickinson's Pharmacy -- The Independent Voice*, a professionally stimulating monthly newsletter available for \$45 a year plus your retail pharmacy's label from Ferdic, Inc., PO Box 367, Las Cruces, NM 88004-0367.

**THE BALTIMORE VETERAN DRUGGISTS ASSOCIATION**, organized in 1926, meets every third Wednesday of the month at Horn and Horn Smorgasbord on Cromwell Bridge Road, Beltway Exit 29. Visitors are welcome. Call Harold Katcoff at (410) 358-7036.

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**PHARMACISTS' REHABILITATION COMMITTEE** For private, confidential referrals call (410) 727-0746 or (410) 328-7513.

**FOR RENT** Ocean City, 122nd St. Luxurious townhouse with 25 foot oceanfront decks, 3 levels, 4 bedrooms, sleeps 10 all extras. Families only. Available week of MPhA Convention, \$1250/week. Also weeks in July and August, \$1500/week. Weeks in September, \$1250/week. Call Joel at (301) 652-8289.

**BOOKS FOR SALE** *Milton College of Pharmacy* catalog published in 1942. *The Extinct Medical Schools of Baltimore* published in 1969 by the Maryland Historical Society. Call SJ Provenza, Pharm.D. at (410) 433-9049.

**PHARMACY WANTED** Pharmacist looking to buy a pharmacy, preferably in a medical center. Some owner financing desired. Call (410) 313-8873.

**PART-TIME PHARMACIST NEEDED** for retail HMO site in Bel Air on Tuesdays and Thursdays from around 5:00 to 8:00 pm. Call Jim at (410) 569-0822.

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